

**“A PROSPECTIVE, RANDOMIZED STUDY COMPARING THE
ANALGESIC EFFICACY OF SCALP BLOCK WITH 0.25% BUPIVACAINE
VS PRE INCISIONAL LOCAL INFILTRATION WITH 0.25%
BUPIVACAINE WITH ADRENALINE (1:400,000) IN PATIENTS
UNDERGOING ELECTIVE CRANIOTOMIES”**

Dissertation submitted to

THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY

In partial fulfillment for the award of the degree of

DOCTOR OF MEDICINE

IN

ANAESTHESIOLOGY

BRANCH X



INSTITUTE OF ANAESTHESIOLOGY AND CRITICAL CARE

MADRAS MEDICAL COLLEGE

CHENNAI - 600003

APRIL 2016

CERTIFICATE OF THE GUIDE

This is to certify that the dissertation titled, “A PROSPECTIVE, RANDOMIZED STUDY COMPARING THE ANALGESIC EFFICACY OF SCALP BLOCK WITH 0.25% BUPIVACAINE VS PRE INCISIONAL LOCAL INFILTRATION WITH 0.25% BUPIVACAINE WITH ADRENALINE(1:400,000) IN PATIENTS UNDERGOING ELECTIVE CRANIOTOMIES” is a bonafide research work done by Dr.R.Balaji in partial fulfilment of the requirement for the degree of DOCTOR OF MEDICINE in Anaesthesiology.

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Institute of Anaesthesiology & Critical care
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Place:

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DECLARATION

I hereby declare that the dissertation titled, “A PROSPECTIVE, RANDOMIZED STUDY COMPARING THE ANALGESIC EFFICACY OF SCALP BLOCK WITH 0.25% BUPIVACAINE VS PRE INCISIONAL LOCAL INFILTRATION WITH 0.25% BUPIVACAINE WITH ADRENALINE(1:400,000) IN PATIENTS UNDERGOING ELECTIVE CRANIOTOMIES ” Has been prepared by me under the guidance of Prof.Dr.Samuel Prabhakaran, MD., Professor of Anaesthesiology, Institute of Anaesthesiology & Critical care, Madras Medical college, Chennai, in partial fulfillment of the regulations for the award of the degree of M.D (Anaesthesiology), examination to be held in April 2016.

This study was conducted at Institute of Anaesthesiology & Critical care, Madras Medical College, Chennai.

I have not submitted this dissertation previously to any journal or any university for the award of any degree or diploma.

Date :

Place : Chennai

DR.R.BALAJI

ACKNOWLEDGEMENT

I am extremely thankful to Dr.R.Vimala MD, the Dean, Madras Medical College, for her permission to carry out this study.

I am immensely thankful and indebted to Prof.Dr.B.Kala,MD,DA, the Director and Professor, Institute of Anaesthesiology & Critical care, for her concern, guidance and support in conducting this study.

I am extremely thankful to Prof.Dr.Samuel Prabhakaran,MD, for his concern, inspiration, meticulous guidance, expert advice and constant encouragement in doing this study.

I am immensely thankful to Dr.D.Shunmuga Priya, MD, for her valuable suggestions and constant motivation in doing my study.

I am extremely thankful to Dr.Catherine Rathinasamy, Dr.N.Sumathy M.D, Dr.Capt.R.Sudhakar, M.D,D.A.,for their support in carrying out this study.

I am thankful to institutional ethics committee for the approval and guidance for this study.

I am thankful to all my colleagues and friends for their help and advice in carrying out this study.

I am grateful to my family members and friends for their moral support and encouragement.

Lastly I am extremely thankful to Almighty and all the patients and family members for willingly submitting themselves for my study.

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Submission title: *A Prospective, randomized study ...
File name: THESIS_FINLA_-_Copy.docx
File size: 1,009.62K
Page count: 112
Word count: 16,990
Character count: 97,939
Submission date: 17-Sep-2015 08:06PM
Submission ID: 571689245

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AIM OF THE STUDY:

To compare the analgesic efficacy of Scalp block with 0.25% Bupivacaine vs Pre Incisional Local infiltration with 0.25% Bupivacaine with Adrenaline(1:400,000) in patients undergoing elective Craniotomies

BACKGROUND:

Various drug regimens have been evaluated for providing post operative analgesia in patients undergoing elective Craniotomies. In this study Scalp block is compared with the traditionally used Pre-Incisional Local infiltration techniques. 60 patients were selected and randomized into two groups with 30 in each group.

- **Group A** patients received Scalp Block with 0.25% Bupivacaine.
- **Group B** patients received Pre-Incisional infiltration with 0.25% Bupivacaine with 1:4,00,000 Adrenaline.

The parameters compared were Intra-Operative Hemodynamics like Heart Rate, Systolic Blood Pressure, Diastolic Blood Pressure, Mean Arterial Pressure. Post-Operative VAS Score, Intra-Operative Opioid Requirements

RESULTS:

There were significant differences in intra-operative hemodynamics between the two groups. Scalp Block resulted in statistically significant reduction in Heart Rate, Systolic Blood Pressure, Diastolic Blood Pressure and Mean Arterial Pressure. There was increased duration of Post Operative analgesia in Scalp Block group when compared with the local infiltration group. The

opioid requirement in the intra-operative period was significantly lesser in Scalp Block group when compared with the local infiltration group. Requirement of rescue analgesic is significantly lesser during early post operative period (Upto 8 hours) in the Scalp Block group when compared with Local infiltration group

CONCLUSION:

In conclusion, Scalp block with 0.25% Bupivacaine is effective and superior to Pre-Incisional Local infiltration with 0.25% Bupivacaine with 1:4,00,000 Adrenaline in attenuating hemodynamic responses to noxious stimuli. Scalp block also provides increased duration of post operative analgesia when compared with local infiltration. Scalp Block also results in significant reduction in intraoperative opioids and post operative rescue analgesic requirements.

KEYWORDS:

Craniotomy, Analgesia, Scalp Block, Local Anaesthetics

INTRODUCTION

Neuroanaesthesia continues to develop and expand. It is a speciality where the knowledge and expertise of the anaesthetist may directly influence patient outcome. Evolution of neurosurgical practice is accompanied by new challenges for the anaesthetist with greater focus on functional recovery of neurological status. The emphasis remains on the

- Maintenance of balanced Anaesthesia with hemodynamic stability
- Ensuring smooth induction and recovery
- Maintenance of adequate Cerebral perfusion pressure
- Avoiding rise in intra-cranial pressure
- Provision of good operative conditions,
- Preservation of neurological function
- Rapid, high-quality recovery.
- Ensuring proper post-operative analgesia

Pain is often referred as the “*fifth vital sign*”. Pain management in patients undergoing craniotomies pose a great challenge to the anaesthesiologists. Post-Craniotomy pain has been gaining so much attention in neuroanaesthesia these days. It is often compounded by the complex nature of surgery, underlying CNS pathology. The necessity to assess the immediate post operative period neurologic status warrants the judicious use of sedative analgesics. Even though craniotomy pain is less severe when compared to other surgical procedures, it has been under treated in the recovery phase for most of the patients.^[13,36,47].

Various factors should be considered to decide on the type of pain modality to be given to the patient. They are the patients co-morbid diseases, psychological status, previous exposure to analgesics, and the type of operation. The multimodal

approach can lower peri-operative morbidity, decrease the duration of hospital stay, and enhance patient satisfaction .

Eventhough a multi pharmacological approach is being universally accepted, medicines and their route of application have to be changed based on the type of operation and hospital resources, and the patient needs.

Intracranial structures vary in their sensitivity towards perceiving the painful stimuli. During the intra operative period, stimuli like 3-pin insertion, skin incision, dural manipulation,dural and skin closing causes different levels of nociception. Painful stimuli is associated with hemodynamic changes like increase in Heart rate and Mean Arterial Pressure.

Noxious stimuli may lead on to variety of implications in neurosurgical patients.

- Hypertension may cause rise in intracranial pressure in patients with impaired autoregulation
- Possibility of intracranial aneurysm rupture
- Incidence of post operative hematoma
- Rise in cerebral Oxygen demand along with hemodynamic alteration as evidenced by cerebral oximetry.

As with other procedures, long term pain syndromes have been identified for craniotomies.

With all the above considerations, Scalp Block forms an important aspect in the multimodal approach to the Post-Craniotomy pain. The following study compares the analgesic efficacy of Scalp Block with traditionally used local wound infiltration technique in providing analgesia to craniotomy patients.

AIMS AND OBJECTIVES

AIM:

The aim of my study is to assess and compare the analgesic efficacy of Scalp block with 0.25% Bupivacaine vs Pre Incisional Local infiltration with 0.25% Bupivacaine with Adrenaline(1:400,000) in patients undergoing Elective Craniotomies .

OBJECTIVES:

To compare the analgesic efficacy of Scalp block with 0.25% Bupivacaine vs Pre Incisional local infiltration with 0.25% Bupivacaine with Adrenaline (1:400,000) in patients undergoing Elective Craniotomies based on

- Intra-operative hemodynamic status
- Post-operative VAS score

POST CRANIOTOMY PAIN

Pain management in patients undergoing craniotomies pose a great challenge to the anesthesiologists. It is often compounded by the complex nature of surgery, underlying CNS pathology. The necessity to assess the immediate post operative period neurologic status warrants the judicious use of sedative analgesics. Even though craniotomy pain is less severe when compared to other surgical procedures, it has been under treated in the recovery phase for most of the patients.^[13,36,47] As with other procedures, long term pain syndromes have been identified for craniotomies.

INCIDENCE OF ACUTE POST CRANIOTOMY PAIN

GLOBAL LEVEL

It has been a general thought that craniotomies are comparatively less painful than other surgeries. This idea was challenged by *De Benedettis et al*^[13] in their study Postoperative pain in Neurosurgery, a pilot study (1996). They proved that the incidence was significantly higher than the previous assumptions. They proposed that 60% of patients have experienced pain in the post operative period. Intensity ranges from moderate to severe pain in two third of study group. It was more during the initial 48 hours of surgery^[13].

Stoneham et al^[39] had sent a postal Questionnaire to 110 patients who underwent craniotomy a year back. They have reported that over half of 110 respondents revealed that post operative analgesic level was inadequate.

NATIONAL LEVEL

Nair et al, conducted a study on evaluation of pain after supratentorial craniotomy. They have used paracetamol as a sole analgesic agent. Study was conducted over a period of 6 months. Post –operative pain was assessed at 8,12,24 and 48 hours using Visual Analog Scale. They have found out that

- 63% patients had inadequate analgesia in first 12 hours.
- 12% of patients complained of severe pain.
- 50% of patient who complained of pain beyond 12 hours developed post operative complications
- Pain has been addressed properly only in 27% patients

PRE OPERATIVE HEADACHES VS POST OPERATIVE PAIN

Headache is one of the manifestation of the underlying CNS pathology. The incidence of preoperative head ache is more in cases of metastatic tumour, secondaries brain, high grade astrocytoma. The incidence of preoperative headache is even more in cases of infra tentorial tumours. It is important to differentiate it from post operative pain.

Gee et al ^[19], did a comparative study on preoperative headache and post craniotomy pain and proposed that it can be differentiated by eliciting the history regarding the site and nature of the pain. Preop headache were mostly dull and continuous, more of visceral nature. Post craniotomy pain is rather somatic, superficial and closely related to the site of surgery

NATURE OF PAIN

Nature of pain ranges from pulsating to pounding headaches that was similar to, what was termed as tension head ache. It was more in females and younger patients. Older people are relatively tolerant to pain. Rarely, the pain was steady and continuous.

PATHOGENESIS PERTAINING TO POST-CRANIOTOMY PAIN:

Post craniotomy pain is typically nociceptive. In majority of patients, it is superficial in origin rather than the visceral one. Pain is invariably due to surgical incision and reflection of underlying muscles. It has been proposed that pain arises from skin, soft tissues and pericranial muscles. It has been proposed that brain parenchyma is relatively insensitive to pain^[13,36].

Traditional theories suggest direct transmission from somatic pain receptors to the brain. And the pain perceived being directly proportional to the extent of injury.^[14]

Recent research, clinical experiments points out that far more complex mechanisms are involved in pain perception. It involves not only a moment- moment analysis of afferent noxious input but also a dynamic process in which it is compared with the past experiences. Various process like sensitization, wind up phenomenon.^[14] are involved.

Transmission of pain requires intact signal processing system involving forebrain and brainstem as far as Post-Craniotomy pain is concerned.

SENSITIZATION

- Component of Chronic Pain
- Acts through peripheral mechanism or through forebrain or spinal cord
- Involves mechanisms like
 - Upregulation of Sensory Sodium Channels
 - Phenotype switching of large myelinated axons
 - Sprouting of nerve fibres within dorsal horn
 - Loss of inhibitory neurons
 - Vanilloid Receptors

WIND-UP

- Involves NMDA and tachykinin NK₁ receptors^[26] for generation
- A frequency dependent phenomenon
- Can be abolished by NSAIDS and opioids

ROLE OF NEURO TRANSMITTERS IN POST CRANIOTOMY PAIN

- There has been increasing evidence that suggests the role of Serotonergic system in pain associated with Chronic Tension-Type and migraine headaches.
These theories have been extrapolated to Post- Craniotomy pain.
- Stimulation of GABA receptors decreases rate of firing in raphe nuclei of serotonergic neurons
- **Marcus et al**,^[28] concluded the role of serotonin in migraine and tension type headaches. They postulated that vascular changes and excessive muscle contraction that has been traditionally associated with these headaches have been preceded by changes in the serotonin level.
- **Cavalotti et al**^[10], pointed out the role of catecholaminergic nerve fibres in pain associated with craniotomy. These fibres are rich in basal region of skull. They are also abundant in perivascular area. These changes coincides with the higher incidence of pain associated with Posterior Cranial fossa repairs and basillar tumour excision.
- **Harner et al** ^[22], in their study regarding the pain management in acoustic neuroma has found out that noxious stimuli often induces variety of central neurotransmitter changes that may lead on to severe post operative pain ,later on proceeding to chronic regional pain syndromes which is often detrimental to post operative patients.

ROLE OF PRE-EMPTIVE PAIN RELIEF IN CRANIOTOMY

- Proposed by *Wall et al*^[43]
- It is based on the development of chronic pain that develops after central neuroplasticity
- Now it has been proposed that appropriate pain relief in the immediate post operative period is necessary to prevent the incidence of chronic regional pain syndromes.

ANALGESIA AFTER CRANIOTOMY:

Following points have to be considered while evaluating and treating pain in neurosurgical patients.

- No standardized protocols for pain evaluation
- Differential sensitivity of different intracranial structures to noxious stimuli
- Further compounded by aphasia, altered GCS or cognitive impairment that is associated with neurosurgical patients
- Difficulties associated with assessing pain in patients on Post Operative Mechanical Ventilation
- Excessive sedation, respiratory depression and vomiting warrants the judicious use of opioids
- Miosis, Vomiting and sedation precludes the use of morphine
- Post operative Seizures warrants the judicious use of Tramadol and Diclofenac
- Increased bleeding risk associated with Paracetamol precludes its use from AV malformation, Aneurysmal clipping and hematoma evacuation

PAIN INSENSITIVE STRUCTURES IN BRAIN :

The following areas of brain are relatively insensitive to surgical and painful stimuli

- Dura over skull convexity
- Arachnoid layer
- Choroid plexus
- Piamater
- Brain parenchyma
- Ependyma

PAIN SENSITIVE STRUCTURES IN BRAIN :

The following areas comprises the pain sensitive areas of brain. Surgical manipulation along these areas are associated with changes in hemodynamics and increase in requirements of opioids and other anaesthetic agents.

Intracranial :

- Falxcerebri
- Cranial venous sinuses
- Dura around venous sinuses and vessels
- Arteries at base of brain
- Arteries of dura (Middle Meningeal artery)

Extracranial :

- Muscles
- Arteries
- Periosteum
- Skin
- Scalp appendages

Nerves :

- Trigeminal Nerve (Fifth cranial nerve)
- Facial Nerve (seventh cranial nerve)
- Glossopharyngeal (Ninth cranial nerve)
- Vagal (Tenth cranial nerve)

ANALGESIC THERAPY FOLLOWING CRANIOTOMY

The following modalities have been considered while providing analgesia to craniotomy patients.

OPIOIDS:

Opioids have been widely used in the treatment of post operative pain. Opioids form the cornerstone in treating post operative pain.

MECHANISM OF ACTION

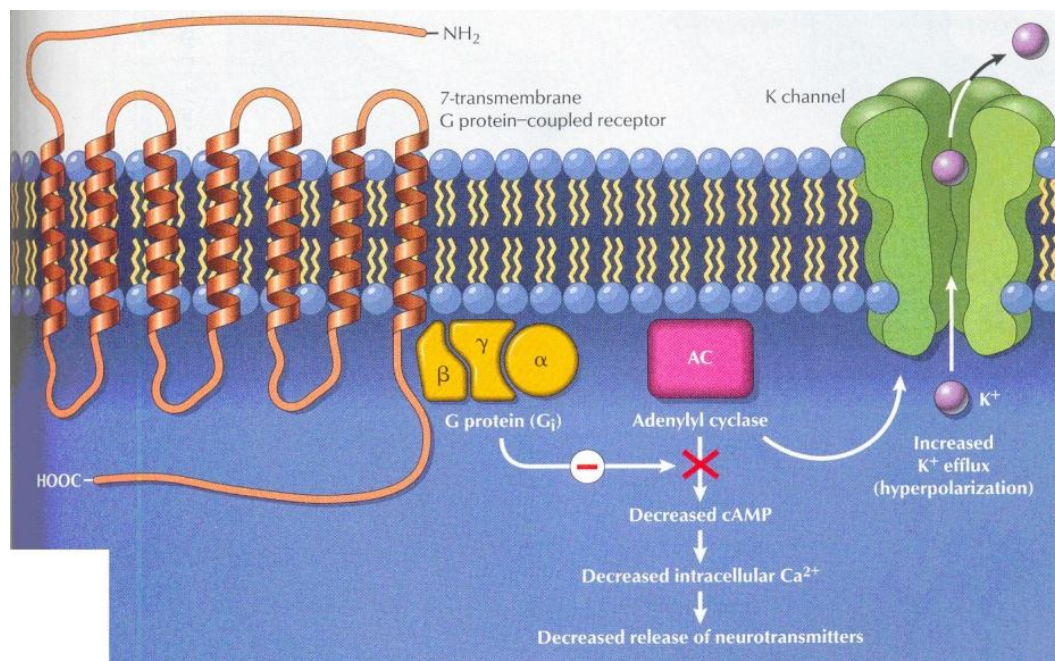


FIGURE : MECHANISM OF ACTION OF OPIOIDS

The various opioids used during neurosurgeries are as follows.

Tramadol

CHEMISTRY

- Cyclohexanol derivative
- Racemic mixture composed of two enantiomers.

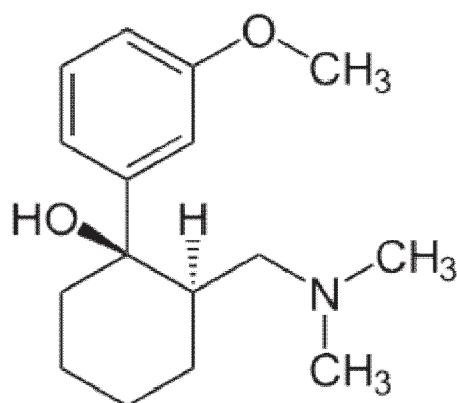
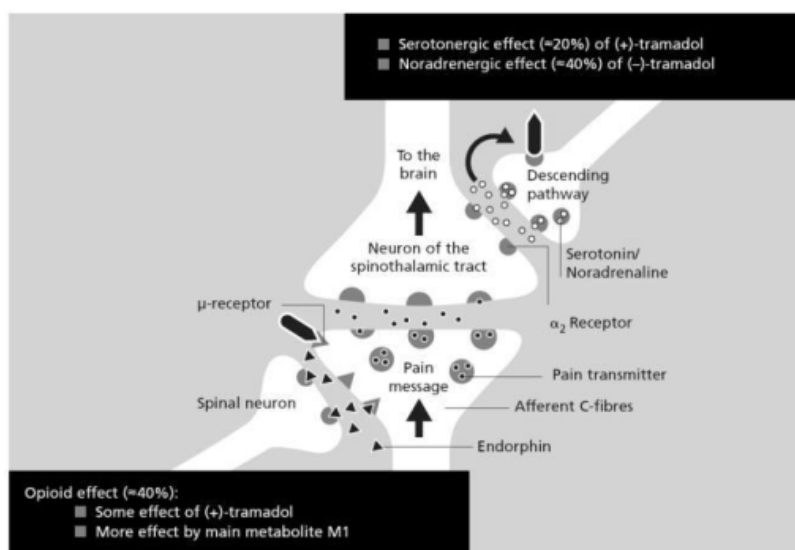


FIGURE 1 TRAMADOL

MECHANISM OF ACTION

- Mu receptors - Weak agonistic activity
- Norepinephrine and 5 hydroxytryptamine – Inhibition of neuronal uptake



ADVANTAGES

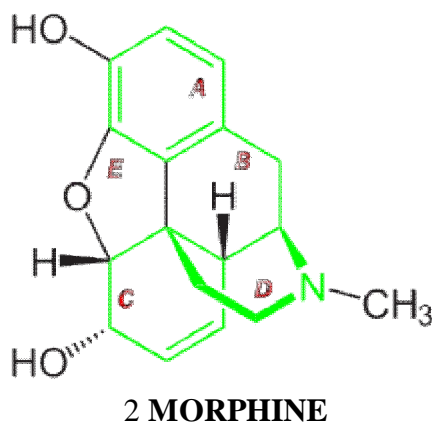
- I. Easy Availability, Lower cost
- II. Effective in mild to moderate pain
- III. Unlike NSAIDS , no effect on platelet function or coagulation
- IV. Used along with other drugs as a part of multimodal analgesia
- V. Less sedation and narcosis when compared to other opioid

LIMITATIONS

- I. Tramadol increases the risk of seizures by reducing the seizure threshold
- II. It is associated with higher risk of post operative nausea and vomiting
- III. In higher doses, other adverse effects of opioids like sedation and respiratory depression occurs

MORPHINE:

CHEMISTRY



Morphine- C₁₇H₁₉NO₃ - Phenanthrene alkaloid

- I. A.BENZENE RING
- II. B & C. UNSATURATED CYCLOHEXANE RING
- III. D. PIPERIDINE RING
- IV. E.TETRAHYDROFURAN RING

LIMITATIONS

- I. Dose dependent depression of ventilation through agonism at *mu* receptors thereby raising the ICT
- II. Sedation – Most common reason for discontinuation of drug. It occurs in 60% patients thereby compounding neurological examination.
- III. Miosis - Due to excitatory action on ANS of Edinger-Westphal nucleus thereby compounding the neurological examination
- IV. Nausea & Vomiting – By direct stimulation of CTZ of fourth ventricle
- V. GI smooth muscle spasm ,Urine retention and itching were the some of the other side effects of morphine

CODEINE

CHEMISTRY

Synthesized by methylation of the 3-hydroxyl group of the Morphine ring.

METABOLISM

Major metabolic Pathway – Formation of Codeine –Glucuronide

Minor Pathway – 5-15% demethylates to form Morphine

ADVANTAGES

Lesser incidence of

- Sedation
- Respiratory Depression
- Miosis, than that of other opioids^[12]

LIMITATIONS

It includes

- Suboptimal pain control
- Demethylation to morphine is dependent on large inter individual differences causing wide range of interpersonal variation

Sudheer et al, conducted study on 60 patients who have undergone elective craniotomy procedures. They compared the analgesic efficacy of PCA Morphine, PCA Tramadol and Codeine. They found that Morphine provide a superior pain relief when compared to Tramadol & Codeine^[40]

The various perioperative complications Pertaining to craniotomy and opioids are

- I. Sedation – Impairs the assessment of neurological status of the patient
- II. PONV - Prolongs ICU stay and risk of rise in intra cranial pressure
- III. Respiratory depression - Causes Hypoventilation thereby causing hypercapnia and rise in intracranial pressure
- IV. Seizures- Drugs like Tramadol decreases seizure threshold thereby precluding its use in neurosurgeries.
- V. Intermittent administration in view of sedation and respiratory depression may cause alternative period of respiratory depression/sedation and inadequate analgesia
- VI. Risk of addiction and dependency
- VII. Precludes patients from early rehabilitation

NSAIDS

The commonly used drugs were Diclofenac Sodium

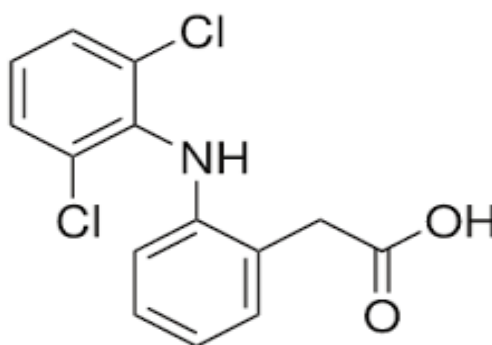


FIGURE 3 DICLOFENAC SODIUM

ADVANTAGES

- Offers satisfactory pain relief when used in combination with other drugs
- Opioid related side effects can be avoided
- Reduces pain and morphine requirement by 25-50%
- Inhibition of Prostaglandins reduces inflammation

Quiney et al. defended use of NSAIDs for control the post-craniotomy pain^[36]

DISADVANTAGES

- Impaired thrombocyte aggregation and increased incidence of post operative intracranial hematoma
- Inhibition of COX-1 isomer causes platelet dysfunction and increases bleeding tendency
- Increased post operative renal complications associated with NSAIDS
- NSAIDS when used alone are not able to provide satisfactory pain relief^[35]

Jones .S.J. et al, pointed out that NSAIDS alone is ineffective in providing analgesia to craniotomy patient^[24]

Alpha – 2 ADRENERGIC AGONISTS

Dexmedetomidine, a highly selective alpha-2 agonist is the commonly used drug

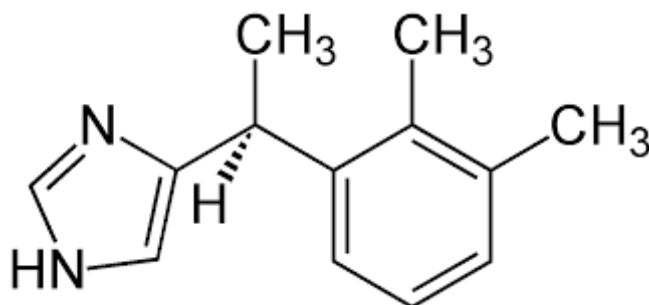


FIGURE 4 DEXMEDETOMIDINE

ADVANTAGES

- Provides sedation and analgesia altogether
- No evidence of respiratory depression
- Can be used as a opioid sparing agent
- Brings arousal immediately thereby facilitating immediate neurological examination
- Sedation often resembles physiological sleep

DISADVANTAGES

- Availability
- Cost
- Safety has to be ensured in neurosurgical patients

Aryan et al, pointed out loading dose must be ideally avoided and higher dose of maintenance agents is required in neurosurgical patients.^[3]

N METHYL-D-ASPARTATE RECEPTOR ANTAGONISTS

Ketamine, a Phencyclidine derivative belongs to this class of drugs.

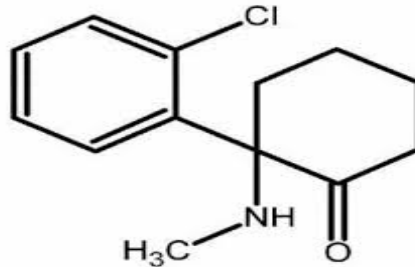


FIGURE 5 KETAMINE

Acts by inhibiting central sensitization to painful stimuli

USES

Sub- Anaesthetic dose along with Local Anaesthetic infiltration is used during skull pin placement

Bowles et al, demonstrated the efficacy of Ketamine in blunting the hemodynamic responses during pin placement^[16]

LIMITATIONS

- Not routinely used, as it causes *increase in intracranial pressure*
- Safety in neurosurgical procedures have not been ensured

LOCAL WOUND INFILTRATION

- *Braun in 1910* – Described the Subcutaneous infiltration of mixture of local anesthetics along with vasopressor agents to achieve hemostasis during craniotomy
- *Hillman et al*^[25] – Conducted the first randomized double blind study to compare local anaesthetic mixture with saline infiltration in craniotomy surgeries. Found out increased hemodynamic stability in Local anaesthetic

group. They advocated the use of local anaesthetic administration prior to surgery for better hemodynamic stability

- **Hartley et al**^[23] - Conducted study on effect of pre incisional local infiltration on hemodynamic stability on children undergoing supratentorial craniotomy. They have found out that rise in HR & MAP were attenuated by injection of local anaesthetic agents

ADVANTAGES

- It is often used in Neurosurgery to **blunt hemodynamic response** and to minimize the **bleeding** during surgical incision
- Minimal postoperative analgesia will be provided if performed after skin closure
- Also **better pain scores and opioid sparing effect** is observed if performed post operatively

LIMITATIONS

- Maximum dose should not **exceed the toxic level** otherwise life threatening complications will occur
- **Intravascular injection** might happen as scalp is a highly vascular structure.
- **Analgesic efficacy is very minor** especially during the post operative period

‘SCALP BLOCK’:

EVOLUTION

PIONEERS

- ***Halstead and Hall*** performed nerve blocks using Cocaine in the 1880s
- ***Harvey & Cushing*** – Introduced the term “regional anaesthesia” in 19th century
- ***Harvey Cushing along with George Crile*** in 1900s combined the use of local/regional anaesthesia along with general anaesthetic technique
- ***Penfield and Christensen et al*^[34]** – Lesser incidence of ominous bleeding when vasopressor saline is administered prior to scalp incision
- ***Braun in 1910*** – Described the Subcutaneous infiltration of mixture of local anesthetics along with vasopressor agents to achieve hemostasis during craniotomy
- ***Hillman et al*^[25]** – Conducted the first randomized double blind study to compare local anaesthetic mixture with saline infiltration in craniotomy surgeries. Found out increased hemodynamic stability in Local anaesthetic group. They advocated the use of local anaesthetic administration prior to surgery for better hemodynamic stability
- ***Hartley et al*^[23]** – Conducted study on effect of pre incisional local infiltration on hemodynamic stability on children undergoing supratentorial craniotomy. They have found out that rise in HR & MAP were attenuated by injection of local anaesthetic agents.
- ***Colley PS, Heavner JE*^[11]** – Proposed that Bupivacaine can be safely used to provide scalp infiltration prior to craniotomies.

- **Bithal et al^[8]** demonstrated that bispectral index values raise along with hemodynamic parameters during head pinning that can be attenuated using local infiltration techniques

TRANSITION FROM SCALP INFILTRATION TO SCALP BLOCK

- **Girvinet et al^[18]** - First demonstrated the scalp block in 1986 for awake craniotomy patients
- **Rubial et al^[37]** in 1992., demonstrated the effect of scalp block on maintaining the hemodynamic stability during craniotomy.
- **Pinosky et al^[35]** pointed out the effect of scalp block on preventing the rise in cortisol and maintaining intra operative hemodynamic stability, and also in providing post operative pain relief.

ANATOMICAL CONSIDERATIONS

OSTEOLOGY

Skull –

- Highly delicate part of axial skeleton
- Functions include protection of brain from external injuries
- Isolation of cerebral circulation
- Allows meninges and CSF to act as buffers
- Upper Part of Skull – Calvaria
- Lower Part – Forms Facial Skeleton

ANATOMY OF SCALP

The scalp refers to the layers of soft tissues which cover the cranial vault.^[46]

EXTENSION

ANTERIORLY :- It extends from the supra-ciliary line of the frontal bone

POSTERIORLY :- To the superior nuchal line. The latter is a low ridge which extends on either side from the midline external occipital protuberance of the occipital bone to the corresponding mastoid process.

LATERALLY :- Extends upto zygomatic arch and External auditory meatus

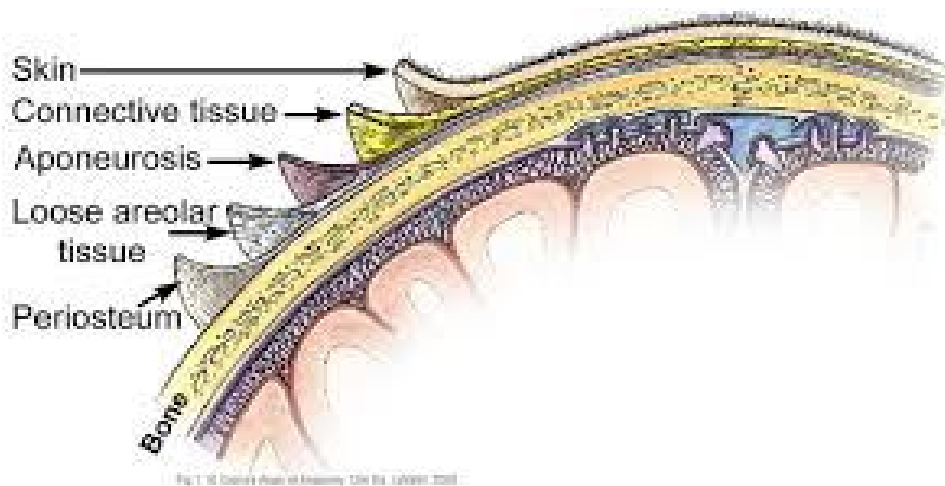


FIGURE 6 LAYERS OF SCALP

Made of five layers

- SKIN
- CONNECTIVE TISSUE
- EPICRANIAL APONEUROIS
- LOOSE AREOLAR TISSUE
- PERIOSTEUM

SKIN

- i. Thick,
- ii. Hairy structure
- iii. Rich in sebaceous glands
- iv. Adherent to epicranial aponeurosis by dense fascial connections

CONNECTIVE TISSUE

- i. Composed of fat lobules embedded in tough layer of fibrous septa.
- ii. More dense in the centre than in the peripheral areas
- iii. Binds skin to adjacent layer of aponeurosis
- iv. Blood vessels and nerves of the scalp run through this layer , Highly vascular area of the scalp

OCCIPITO FRONTALIS MUSCLE

It is composed of two bellies

Occipital belly

- Small and separate
- Arise from lateral two third of superior nuchal line
- Nerve supply: Posterior auricular branch of facial nerve

Frontal belly

- Arise from skin of the orbit mingling with corrugators supercilli and orbicularis oculi
- Nerve Supply: Temporal branch of Facial Nerve



EPICRANIAL APONEUROSIS/GALEA APONEUROTICA

- i. Aponeurosis is the layer of fibrous sheet
- ii. Freely movable over the pericranium
- iii. Extension
 - Anteriorly: Receives frontalis insertion
 - Posteriorly: Receives occipitalis insertion and attached to external occipital protuberance
 - Laterally :Attached to superior temporal line and sends attachments to zygomatic arch over the temporal fascia

LOOSE CONNECTIVE TISSUE

- i. Fourth layer of scalp
- ii. Made of loose areolar tissue
- iii. Extension
 - Anteriorly :- To the eyelids because of absence of bony attachments
 - Laterally :- To the level of superior temporal lines
 - Posteriorly :- Superior nuchal line

- iv. Responsible for the mobility of the scalp over the calvaria
- v. Surgeon mobilize pericranial flap because of this mobile layer
- vi. Blood in this layer can track freely over the scalp accounts for orbital haematoma following craniotomy/cranial trauma

PERIOSTEUM

- i. Also known as pericranium
- ii. Loosely attached to bone surface but it is tightly adhered to the suture lines of the skull.
- iii. Suture ligaments then bind it to the endocranium
- iv. Blood collection wont cross the suture line because of tight adherence resulting in cephalohaematoma.

BLOOD SUPPLY

- i. Scalp is a highly vascular structure
- ii. Receives blood supply from both internal carotid artery and external carotid artery
- iii. The two arterial system anastomose over the temple

INTERNAL CAROTID SYSTEM: It supplies scalp through the ophthalmic branch.

- **SUPRATROCHLEAR ARTERY** - Middle of fore head
- **SUPRAORBITAL ARTERY** - Lateral forehead

EXTERNAL CAROTID SYSTEM.

- **SUPERFICIAL TEMPORAL ARTERY** - Parietal and Frontal branches
- **OCCIPITAL ARTERY** - Posterior part of scalp
- **POSTERIOR AURICULAR ARTERY** – Region around the auricle

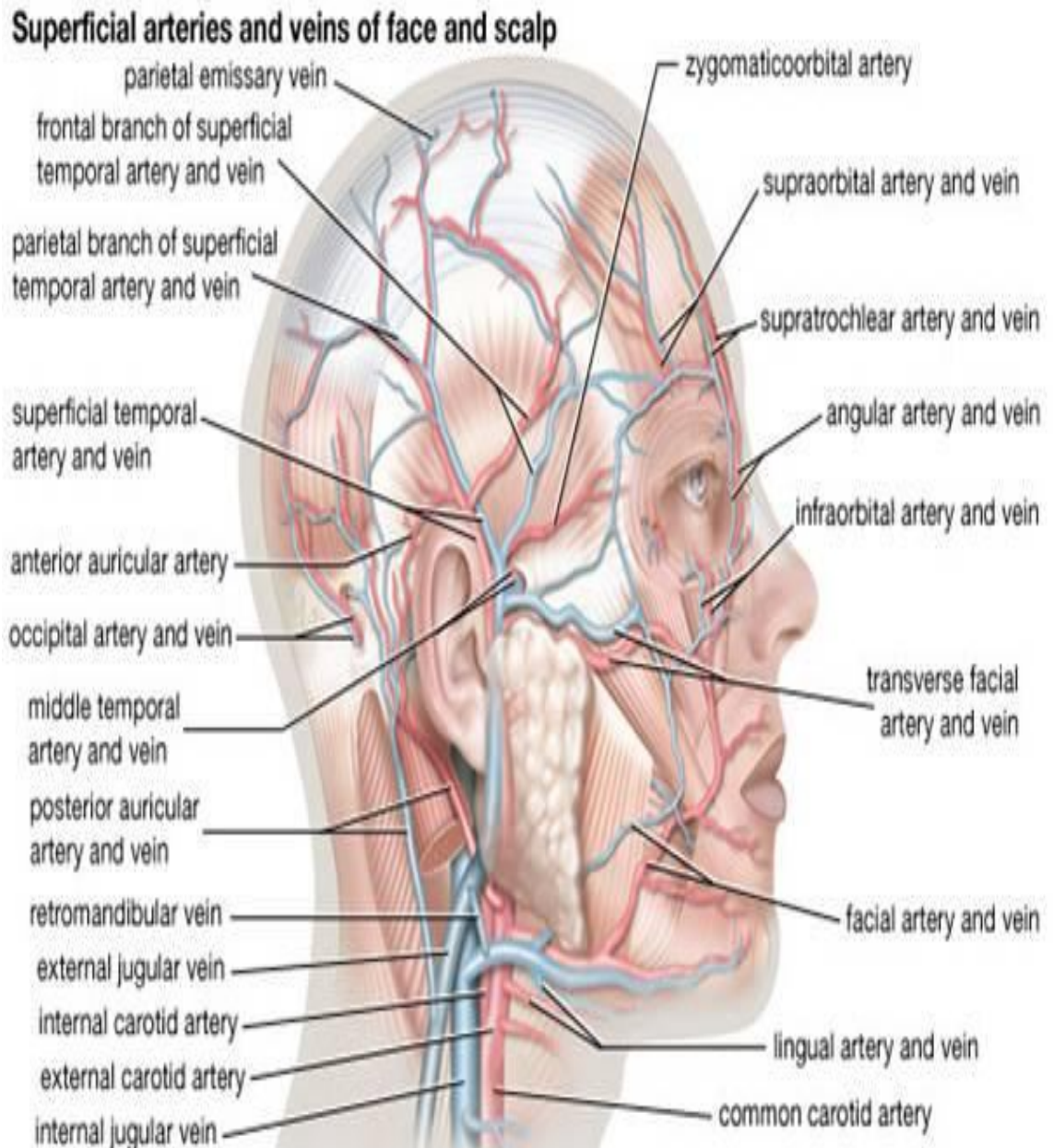


FIGURE 7 ARTERIAL SUPPLY AND VENOUS DRAINAGE OF SCALP

NERVE SUPPLY OF SCALP

SUPRAORBITAL NERVE

- Terminal branch of frontal division of trigeminal nerve
- Passing via the supraorbital foramen, it gives off innervations to the upper eyelid
- After supplying the conjunctiva, it ends as
 - a. *MEDIAL BRANCH* perforates the frontalis muscle.
 - b. *LATERAL BRANCH* perforates the aponeurosis.

INNERVATION

- Skin of the Forehead
- Conjunctiva
- Frontal Sinus
- Skin of the upper eyelid
- Both branches also supply the pericranium

SUPRATROCHLEAR NERVE

- Branch of the frontal nerve that arises from the ophthalmic division of trigeminal nerve. Smaller than the supra orbital nerve
- Passing above the pulley formed by the superior oblique muscle, and gives off a branch that joins nasociliary nerve
- It exits the orbit between the superior oblique and the supraorbital foramen, ascends on to the forehead between the frontalis muscle and corrugators supercilli

INNERVATION

- Lower part of the forehead
- Conjunctiva
- Skin of the upper eyelid

ZYGOMATICOTEMPORAL NERVE

- Derived from the maxillary branch of trigeminal nerve..
- Courses through the lateral wall of the orbit in a groove in the zygomatic bone receives a branch of communication from the lacrimal nerve
- Then it passes through the zygomaticotemporal foramen thereby entering the temporal fossa
- In the temporalis fossa, it ascends between bone and the temporalis muscle within its substance
- Then it pierces the temporal fascia, after giving of a branch it runs towards the lateral angle of the orbit.

GREATER OCCIPITAL NERVE

ORIGIN

- Arises from the dorsal rami of second cranial nerve.
- It originates in the posterior neck in lateral relation to atlantoaxial joint

COURSE

- Ascends in the posterior aspect of neck over the dorsal surface of the Rectus Capitis posterior Major muscle
- Then it turns dorsally to pierce the Semispinalis Capitis
- It runs a short distance rostrally and lies deep to the Trapezius muscle.

- Runs slightly inferior to the Superior nuchal line by passing above an aponeurotic sling formed by Trapezius and Sternocleidomastoid
- Then it lies immediately medial to the occipital artery

INNERVATION:

- It provides sensory supply to the posterior scalp.

LESSER OCCIPITAL NERVE OR SMALL OCCIPITAL NERVE

- One of the four cutaneous branches of cervical plexus.
- Arises from the ventral rami of the second cervical nerve
- Curves around the Sternocleidomastoid muscle and ascends along the posterior border of the muscle.
- Then it perforates the deep fascia and continues to run behind the auricle
- Finally it communicates with the Greater Occipital Nerve, Greater Auricular Nerve, and the Posterior Auricular branch of the Facial Nerve.

ANATOMICAL VARIATIONS

- The smaller occipital varies in size, and is sometimes duplicated.
- .This branch is occasionally derived from the greater occipital nerve

INNERVATION:

- Lateral area of the head posterior to the ear.
- Auricular Branch - Skin of the superior and posterior part of the auricle

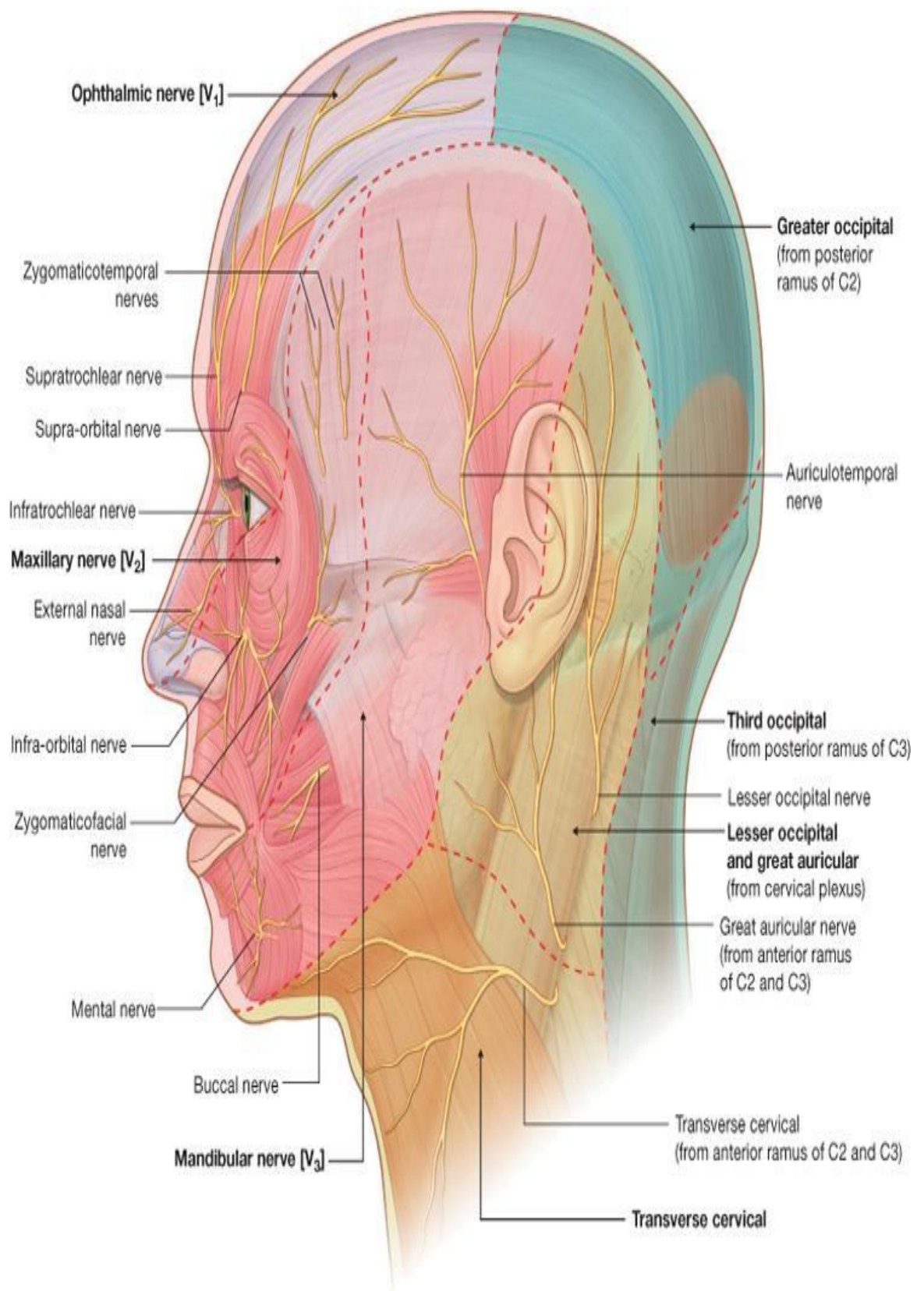


FIGURE 8 NERVE SUPPLY OF SCALP

SENSORY INNERVATION TO MENINGES

Meninges is innervated by

- Meningeal branch of Trigeminal Nerve
- Meningeal Branch of Vagal Nerve
- Upper Cervical Spinal Nerves

ANTERIOR CRANIAL FOSSA

- Trigeminal nerve, Ophthalmic Division
- Also by Nasociliary Branch

MIDDLE CRANIAL FOSSA

- Trigeminal Nerve – Ophthalmic, Maxillary & Mandibular division

POSTERIOR CRANIAL FOSSA

- C2, C3 Spinal Nerves supplying dura near Foramen Magnum
- Twigs from Vagal & Hypoglossal Nerve to the dura around Tentorium Cerebelli

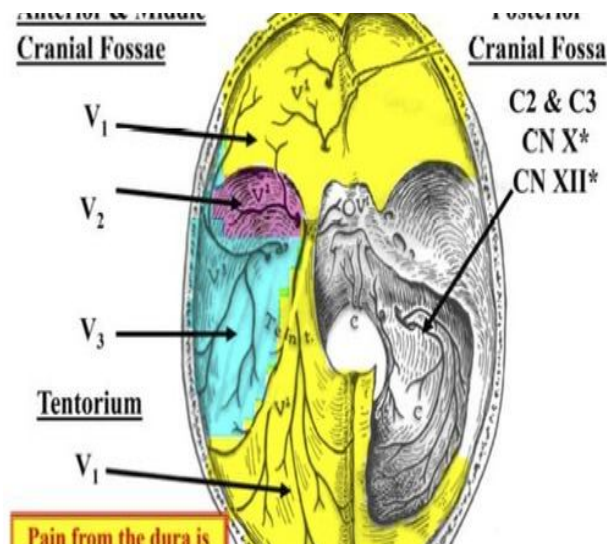


FIGURE 9 INNERVATION OF MENINGES

SCALP BLOCK:

Technical Description

Following nerves are blocked in the technique

Supraorbital Nerve

- Blocked at the supraorbital notch as the nerve emerges from the orbit.
- The supraorbital notch is palpated
- Needle is inserted approximately 1 cm medial to the supraorbital foramen perpendicular to the skin,

Supratrochlear Nerve

- The supratrochlear nerve is usually blocked as the nerve emerges from the supraorbital margin
- It can also be blocked by a medial extension of the supraorbital block.

Auriculotemporal Nerve

- Blocked by infiltration over zygomatic process, at the level of tragus
- Blocked about 1 to 1.5 cm anterior to the ear
- Inadvertent injections into superficial temporal artery must be avoided

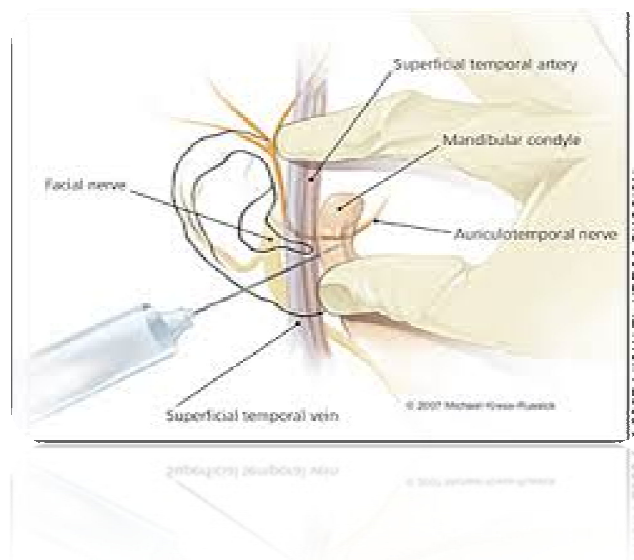
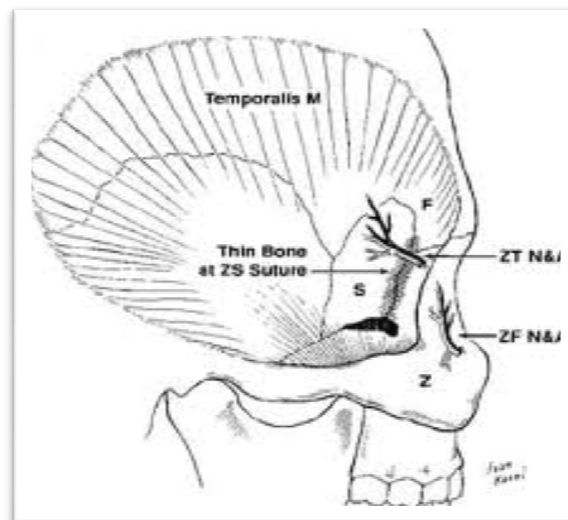


FIGURE 10 AURICULOTEMPORAL NERVE BLOCK

Zygomaticotemporal Nerve

- Blocked by infiltration from the supraorbital margin to the of the zygomatic arch.
- The nerve ramifies as it enters the temporalis fascia
- Hence infiltration is recommended in both superficial and deep plane of the muscle



Greater Occipital Nerve

- Blocked approximately midway between the mastoid process and the occipital protuberance
- About 2.5 cm lateral to median nuchal line.
- Palpation of occipital artery and injecting drug medially often proves to be a reliable landmark
- Inadvertent injections into occipital artery must be avoided

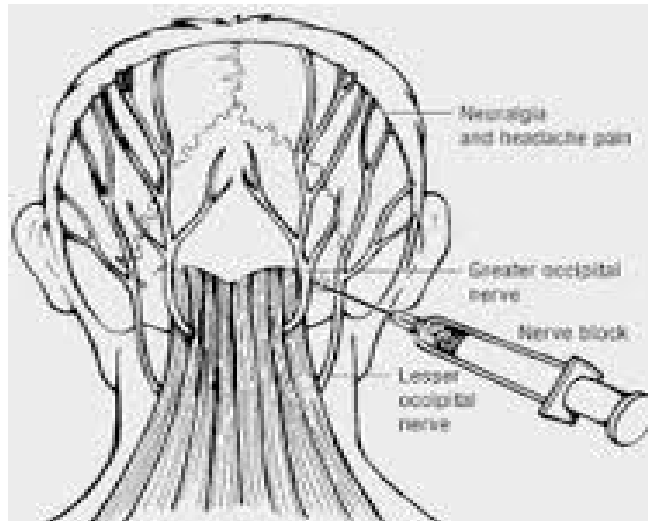


FIGURE 11 OCCIPITAL NERVE BLOCK

Lesser Occipital Nerve

- Blocked by infiltration along the superior nuchal line
- It is about 2.5 cm lateral to the greater occipital nerve block.

The volume of local anesthesia administered at each site can vary from 2 to 5mL of 0.25% to 0.5% Bupivacaine

COMPLICATIONS/CONTRAINDICATION

As far as scalp block is concerned, complications are relatively uncommon

- Acute raise in local anaesthetic concentrations can occur following scalp block because of the high vascularity of the scalp. Can be prevented by adding adrenaline to the local anaesthetic mixture. Hence high degree of vigilance is warranted in the earlier period to monitor signs of *local anaesthetic toxicity*.
- *Archer et al^[2]*, reported the incidence of *seizures* after local anaesthetic administration. But the cause of seizures was questionable since patients were having previous history of intractable seizures
- *Hypotensive episodes* have been reported and hence close blood pressure monitoring is warranted

- *Okuda et al^[30]* reported *inadvertent injection of local anaesthetic into the intrathecal space* during an occipital nerve block. Hence in the presence of bone defect occipital nerve block is relatively contraindicated.
- As in other head and neck blocks, inadvertent intra-arterial injection may cause retrograde flow into cerebral circulation thereby causing *apnoea, loss of consciousness, sudden cardiac arrest*. But no cases have been reported in scalp block
- The proximity of the facial nerve during auriculotemporal nerve block makes *facial palsy* as a potential complication. Hence careful superficial administration is needed to prevent the facial palsy.
- When local anaesthetic agent is mixed with a vasoconstrictor, *hypertension* can result from inadvertent intravascular injection or systemic absorption. But the incidence is much lesser when careful aspiration is performed prior to injection.
- *Infections* is always a concern with any regional procedure. But no incidence of infections have been reported so far in the literature.
- Relative contraindications include *history of bleeding diathesis* and *history of allergy to local anaesthetic agents*

APPLICATIONS AND FUTURE PROSPECTS

“SCALP BLOCK” FOR POSTOPERATIVE PAIN

Bloomfield et al^[9], conducted study on the effect of scalp infiltration on intra operative hemodynamics and post operative pain relief. They found out that scalp block provides excellent pain relief when compared to the control group.

“SCALP BLOCK” IN PEDIATRIC PATIENTS

- Scalp blocks have been successfully used in children for several years. As in adults, pain will increase morbidity in the immediate postoperative period in neonates and children,^[4]
- Great auricular nerve blocks has been successfully used in children undergoing tympanomastoid surgery .They have reported lesser incidence of pain related morbidity in these patients. Also sedative analgesics like opioids can be avoided^[41]
- Future prospects in pediatric patients including utilization of scalp block for deep brain stimulation and also in the treatment of dystonias

“SCALP BLOCK” AND CHRONIC PAIN MANAGEMENT

- Recent investigations have emphasized the role of scalp block on long term and chronic pain management.
- *Batoz et al*^[6] studied the effect of post operative Ropivacaine scalp infiltration on acute and persistent postoperative pain in patients undergoing intracranial tumor resection. Two months after the surgery, persistent pain was significantly lower in group who have received scalp block rather than Fentanyl group/saline infiltration group..
- Thus, Perioperative local anesthetic infiltration may also potentially decrease the incidence of persistent postoperative pain.

OTHER USES

Occipital nerve block can also be used in the following scenarios.

- Occipital Neuralgia
- Cervicogenic Headache
- Cluster Headache
- Migraine

FUTURE PROSPECTIVES

Future prospective includes its usage for

- Stereotactic Radio Surgery
- Deep Brain Stimulation

PHARMACOLOGY OF BUPIVACAINE

Bupivacaine is a long acting amino amide group of local anaesthetic agent.

CHEMICAL NAME:- 1-Butyl-2',6'-pipecoloxylidide monohydrochloride, monohydrate.

NATURE :- White crystalline powder

SOLUBILITY :- Freely soluble in ethanol, water soluble, and minimally soluble in acetone.

CHEMICAL STRUCTURAL FORMULA:

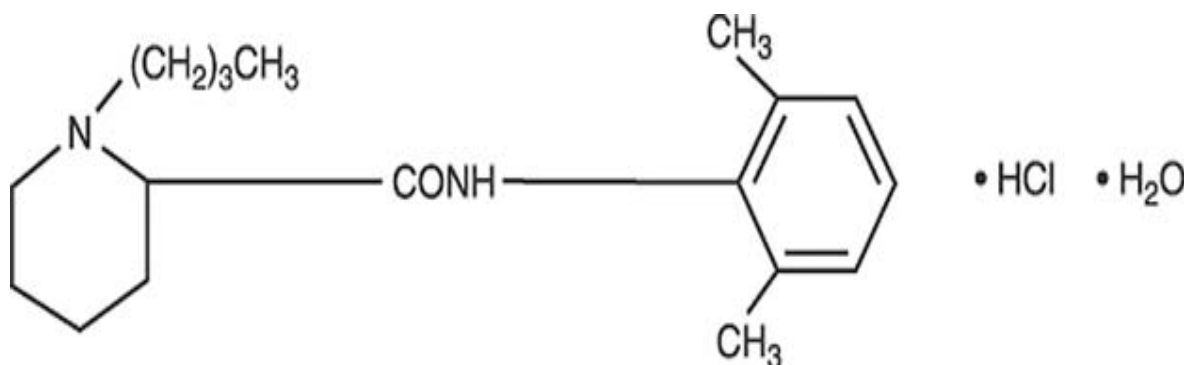


FIGURE 12 MOLECULAR STRUCTURE OF BUPIVACAINE

-**pKa** = 8.1 (causes longer onset of action)

-**pH of plain solution** = 4.5 to 6.0

-**pH of vasoconstrictor containing solution** = 3.0 to 4.5

MECHANISM OF ACTION:

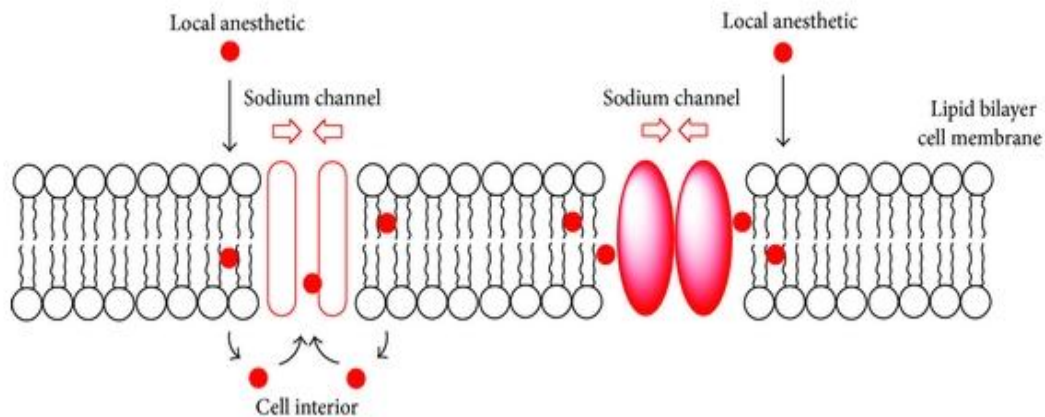


FIGURE 13 MECHANISM OF ACTION OF LOCAL ANAESTHETICS

LA crosses the cell membrane,



Inhibition the sodium channel from cytoplasmic side



Inhibition of propagation of the action potential

The sodium channel protein consist of three subunits, forming a voltage-sensitive and sodium-selective channel. Various isoforms are present in different organs like muscle, heart, central nervous system, peripheral nervous system, etc.

PHARMACO KINETICS

VOLUME OF DISTRIBUTION :- 73 Litres

ELIMINATION HALF LIFE :- 210 mins

CLEARANCE :- 0.58 litres/min

PLASMA PROTEIN BINDING :- 95%

METABOLISM:- Mainly by liver microsomal enzymes and very little minute amount by plasma cholinesterases. By N-alkylation to pipecolyloxylidine

EXCRETION: Through kidneys

ONSET OF BLOCKADE:- Usually occurs in 6-10 mins

PRIMARY DETERMINANTS

- I. Proximity of the injected LA agent - Closer to the nerve, the lesser the time required to diffuse into the nerve
- II. pH of that tissue .
- III. Size of the nerve fibre :- Onset of action will be quicker if the nerve is small in size, delayed if nerve is larger in size.
- IV. Addition of additives

DURATION OF BLOCKADE :-

The determinants of the duration are

- The rate of clearance of the local anesthetic drug :- Rate of clearance depends upon the blood supply of the local tissue. Hydrophobic drugs produce longer blockade due to slower clearance
- Drug dosage: - Larger the dose of drug, longer the duration of the blockade. This is understood by the longer time needed to clear the larger amount of drug injected
- Addition of additives

ADVERSE REACTIONS

It is mainly due to sudden raise in plasma concentrations secondary to accidental intravascular administration, increased rate of absorption and decreased clearance rate.

CNS COMPLICATIONS:

1. Excitation or depression.
2. Nervousness, dizziness
3. Blurred vision, tremors
4. Drowsiness, convulsions
5. Unconsciousness, respiratory arrest
6. Nausea, vomiting, chills
7. Miosis of the pupils, or tinnitus

CVS COMPLICATIONS:

1. Depression of the myocardium
2. Hypotension
3. Cardiac arrest.

Other adverse reactions are hypersensitivity, idiosyncrasy, diminished tolerance, urticaria, edema.

CONTRAINDICATIONS:-

Known history of Hypersensitivity to amide local anaesthetics or other components of Bupivacaine solutions.

Obstetric Para cervical block with higher concentrations due to risk of fetal bradycardia and cardiac arrest.

DRUG INTERACTIONS & CLINICAL SIGNIFICANCE:-

Concurrent administration of Epinephrine containing anaesthetic agents with MAO inhibitors/Tricyclic antidepressants results in severe prolonged hypertension. Persistent hypertension or cerebrovascular accidents may occur if they are used with vasopressors or Ergot type of alkaloids.

OTHERS:-

No studies have been conducted to determine the mutagenic potential of the drug

Long term effects on fertility has not been determined

Category C class drug in pregnancy

Dose reduction warranted in geriatric patient

Secreted in breast milk – To be carefully administered in nursing mothers

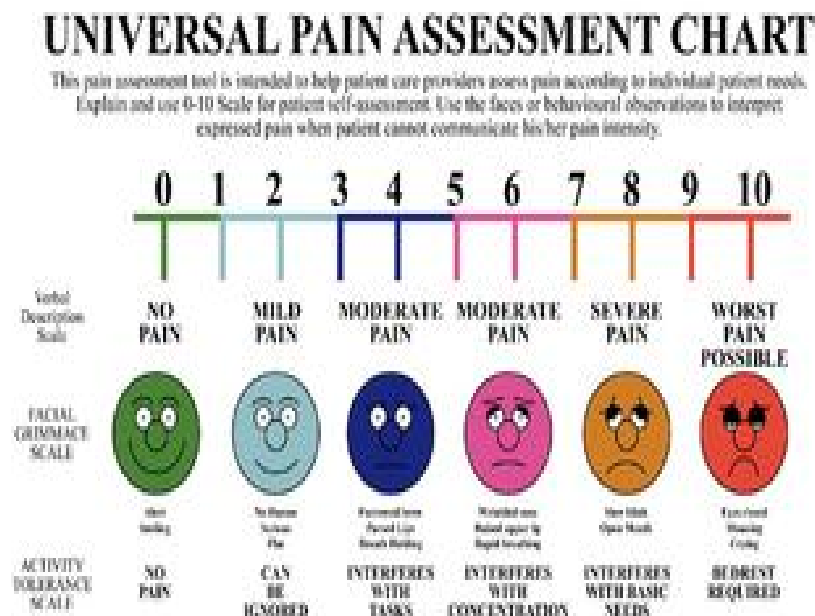
Bupivacaine with Epinephrine 1:200,000 contains Sodium Metabisulfite, known to cause asthma exacerbations in susceptible individuals

PAIN ASSESSMENT METHODS

- Pain is defined as ‘ *An unpleasant sensation and emotional experience associated with actual or potential damage to tissues or described in terms of such damage*’
- Considered as the “ **FIFTH VITAL SIGN**”

VISUAL ANALOGUE SCALE:

- Unidimensional measure of pain sensitivity
- Has a horizontal line that is 10cm in length
- Word descriptions have been described at both end of the scale.
- Patient has to make mark at a point in that scale depending upon the severity of pain
- The VAS score will be obtained by measurement in centimetre from the left end of the line to the point which is marked by the patient.



REVIEW OF LITERATURE

In the year 1990, *Engberg et al*⁽¹⁵⁾, compared the effect of Scalp infiltration with placebo on hemodynamic changes and Cerebral Arterio-venous oxygen content changes(AVDO2) during craniotomy procedures. 20 patients undergoing supratentorial craniotomy were randomly assigned into two groups. Group I received scalp infiltration with 0.5% Bupivacaine. Control group received scalp infiltration with saline mixture. Anaesthetic procedure was standardized between two groups. Significant raise in MAP values was noted in the control group. Also, saline group also had significantly lower values of AVDO2. This points out that saline group was associated with increase in CBF and cerebral hyperperfusion. Hence they concluded that regional anaesthesia during craniotomy procedures was associated with reduction in Cerebral blood flow thereby reducing the intracranial pressure.

In the year 1992, *Rubial M et al*⁽³⁷⁾, assessed the efficiency of scalp block on attenuating the hemodynamic response with regard to skull pin placement. 34 patients were randomly divided into three groups. Group I received supplementary Fentanyl during skin placements. Group II received local infiltration with Mepivacaine. Group III received scalp block with Mepivacaine. They have observed that hemodynamic responses were higher in group I than in other groups. They also found that hemodynamic response in scalp block group was comparatively lesser than that of local infiltration group

In the year 1997, *Pinosky et al*⁽³⁵⁾ conducted a study to assess the effect of Scalp block with Bupivacaine on hemodynamic responses on elective craniotomy procedures. 21 patients were randomly allocated in each group. Group I received Scalp block with 0.5% Bupivacaine. Group II received Scalp block with plain saline. Hemodynamic responses that were monitored include systolic blood pressure(SBP),

diastolic blood pressure(DBP) and mean arterial pressure(MAP). End tidal concentration of Isoflurane was also noted. They were monitored during 5 mins after induction during pinning and 3 mins after pinning.They have observed that scalp block with 0.5% Bupivacaine blunts the hemodynamic response to skull pinning. There were no additional requirements of opioids or end tidal Isoflurane in scalp block group.On the other hand, nine out of ten patients require additional analgesics agents during skull pinning.

In the year 1998, *Bloomfield et al* ⁽⁹⁾, conducted study on the effect of scalp infiltration with Bupivacaine on intra operative hemodynamics and post operative pain relief. The study was conducted on 36 patients undergoing elective craniotomy procedures. Group I received scalp infiltration with 0.25% Bupivacaine with Adrenaline 1:2,00,000. Group II received saline infiltration. HR, SBP,DBP,MAP were compared . They were compared after induction, during scalp infiltration and during dural and skin closure. Post operative pain relief was assessed using VAS score.It has been found that scalp infiltration with Bupivacaine was effective in blunting hemodynamic responses during pin placement and skin incision. But there was no significant difference between two groups during dural closure. And there was no significant difference in post operative VAS score between the two groups.

In the year 2000, *Ozkose et al*, ⁽³¹⁾ compared the effect of local infiltration versus intravenous administration of Inj.Fentanyl 3 minutes after Mayfield skull pin placement based on the hemodynamic response.45 patients were randomly allocated into three groups. Group I received intravenous Fentanyl during pin placement. Group II received local infiltration with 2% Lidocaine. They observed that hemodynamic responses were comparatively lesser in patients who have received local infiltration with Lidocaine rather than those who have received intravenous Fentanyl.

In the year 2001, *Watson et al*,⁽⁴⁴⁾ compared the effect of nerve block versus subcutaneous infiltration during stereotactic frame placement. Thirty patients were randomly assigned into two groups. Group I received scalp block and Group II received local infiltration prior to stereotactic frame placement. They have observed that visual analog scale pain scores were greater with local anaesthetic injection. They have concluded nerve blocks was less painful when compared with scalp infiltration

In the year 2001, *Anil Agarwal et al*,^[1] compared the analgesic efficacy of intravenous Ketamine and local infiltration during skull pin placement. The study design was randomized, placebo controlled and double blinded. 40 patients were randomly assigned into four groups.

- Group I received iv saline administration followed by saline infiltration
- Group II received IV Ketamine with saline infiltration
- Group III received iv saline administration with infiltration with 1% Lignocaine
- Group IV received iv Ketamine administration followed by 1% Lignocaine infiltration

They found out that hemodynamic response to pin insertion is least to in group IV and lesser in Group III, whereas it is significantly higher in placebo group and group II.

In the year 2001, *Nguyen et al* ^[29], conducted a study to determine the efficacy of Scalp Block on post operative period pain score & requirement of analgesics in the 48 hours of post operative period.

The study design was double blinded. They have selected the patients between the 18-70 years of age undergoing supratentorial craniotomy. Patients were randomly enrolled into two groups.

- **Group A** received Scalp Block with 20 ml of 0.75% Ropivacaine
- **Group B** received scalp Block with 20 ml of 0.9% NaCl

Anaesthesia protocol was standardized. End tidal Isoflurane was maintained between 0.25-1% & Inj.Sufentanyl infusion was maintained at the rate of 0.1-0.5µg/kg/min. VAS was assessed at 4,8,12,16,20,24 & 48 hours after surgery. Codeine Phosphate was given at request every 3-4 hours. They have concluded that median VAS Score were less in Group A patients who have received Scalp Block with 0.75% Ropivacaine. Also the requirement of rescue analgesics were comparatively lowering patients who have received Scalp Block with 0.75% Ropivacaine. They have affirmed that Pre Incisional Scalp Block with local anaesthetic mixture reduces the median VAS Scale and also the requirement of rescue analgesics.

In the year 2002, *Biswas et al^[7]*, have conducted a placebo controlled, prospective ,randomized double blind study. They have evaluated the efficacy of Pre-Incisional Scalp infiltration with 0.25% Bupivacaine on post operative analgesic requirements and also in post operative pain perception. Forty patients undergoing elective supratentorial craniotomy of physical status I & II were selected.

- **Group A** received Pre operative Scalp block with 0.25% Bupivacaine
- **Group B** received Pre operative Scalp Block with 0.9% NACL

Parameters observed were Pre incisional & post Incisional HR,SBP,DBP,MAP were recorded. VAS score was used to assess post operative pain relief at intervals of 1,6,12,24 & 48 hours. Inj.Diclofenac Na was used as the rescue analgesic.

They have found that Scalp block with 0.25% Bupivacaine delayed the need of rescue analgesic till 480 mins when compared with 30 mins in placebo group.

They concluded that Bupivacaine delayed the requirement of the first dose of the rescue analgesic in their study.

In the year 2006, *Bala et al*^[5], assessed the efficiency of Scalp block with 0.5% Bupivacaine in Craniotomy patients on post operative pain relief. They have selected 40 patients of ASA I or II undergoing supratentorial craniotomy. They were randomly divided into two groups.

- **Group B** received Scalp block with 0.5% Bupivacaine with 1:4,00,000 Adrenaline
- **Group S** have received 0.9% NACL with 1:400,000 Adrenaline

Numerical Rating Scale was used to assess the pain @ 30 minutes, 1,2,4,6,12 hours post operatively. Inj.Tramadol IV was used as rescue analgesic. They have found out that 60% patients in Group S experienced moderate to severe pain as compared to 25% patients in Group B. Median pain scores upto 6 hours were significantly lower in Group B.

Number of doses of rescue analgesic is also lower in Scalp Block group. They have concluded that Scalp Block using 0.5% Bupivacaine significantly reduce the severity of pain in patients undergoing craniotomy.

In the year 2006, *Ayoub et al*^[4], conducted a study to compare the analgesic efficacy of scalp Block versus intravenous administration of Morphine. The study design was randomized, prospective and double blinded. They conducted study on 60 patients. They were randomly enrolled into two groups. Post operative analgesic efficacy was compared using numerical pain rating scale. They have concluded that quality of analgesia provided by Scalp Block was similar to that of IV Morphine. They have also pointed out that incidence of post operative nausea and vomiting was more with the morphine group when compared with Scalp Block group.

In the year 2009, *Geze et al*,⁽²⁰⁾ compared the effect of scalp block & local infiltration on hemodynamics during skull pin placement. 45 patients were randomly allocated into three groups. Group I received saline infiltration, Group II received Local Anaesthetic infiltration and group III received Scalp block. Responses monitored were HR,SBP, DBP, Serum Cortisol and ACTH before and after skull pin placement. They have found out that all the above mentioned variables were significantly lower in scalp block group. Hence they concluded that scalp block was effective in attenuating hemodynamic response and stress response to skull pin placement when compared to local anaesthetic infiltration

In the year 2013, *Hansen et al*,⁽²¹⁾ conducted a systemic review on post craniotomy pain relief. Four treatment modalities and a total of 519 patients & nine RCTS were compared. They have compared the following modalities of pain relief

- Scalp infiltration (5 Randomized studies)
- Scalp nerve block(2 Randomized studies)
- Parecoxib administration(one study)
- Patient controlled analgesia using morphine(One study)

They concluded that, Parecoxib has a minimal effect in controlling post operative pain relief. Morphine reduces other analgesic requirements but increases the incidence post operative nausea and vomiting. Scalp infiltration is less effective in producing post operative pain relief when quality of pain relief and duration is concerned. Scalp block with local anaesthetic agents produces pain relief for about 6 hours of immediate post operative period. And the incidence of nausea and vomiting is much lesser when compared with other groups

MATERIALS AND METHODS

After getting the Approval of Institutional Ethics Commitee, informed consent from the patients, this study was done in 60 patients coming under American Society of Anaesthesiology- 1, and ASA- 2 of either male or female and aged between 18-65yr, who undergo elective craniotomy surgery in Madras Medical College hospital. This a prospective, randomised, double blinded,controlled study.

The study was conducted in Rajiv Gandhi Government General Hospital, Madras Medical College. The patients were randomised into two groups of 30 patients each by closed envelope method.The patients were blinded to the group they belong.

INCLUSION CRITERIA:

Age	:	18 – 65 years
Weight	:	BMI < 30 Kg/m2
ASA	:	I & II
Surgery	:	Elective
Mallampatti scores	:	I & II

Patients who have given valid informed consent.

EXCLUSION CRITERIA:

- Skin conditions precluding the block
- Patients posted for emergency surgery
- Patients with allergy to local anaesthetics
- Preoperative opiod dependence
- Lack of written informed consent
- Patients not satisfying inclusion criteria
- Craniotomy for Anerysmal Clipping

- Patients undergoing Craniotomy in sitting Position
- Patients with poor Preoperative/Post operative GCS
- Patients requiring elective Post operative Ventilation
- Patients with coagulation abnormalities

MATERIALS

- 100mm,22.G needle
- Monitors – ECG,NIBP,SPO2,ETCO2,End tidal gas monitoring
- Bupivacaine(0.25%) Dilution
- Bupivacaine 0.25% dilution with Adrenaline in 1:4,00,000
- Sterile drapes
- 5ml Syringe
- Visual Analogue Scale

PARAMETERS OBSERVED

Primary Outcome

- Intra-Operative Hemodynamics
 - Heart Rate
 - Systolic Blood Pressure
 - Diastolic Blood Pressure
 - Mean Arterial Pressure
- Post-Operative VAS Score

Secondary Outcome

- Intra-Operative Opioid Requirements

ANAESTHESIA PROTOCOL

- The patients satisfying the above mentioned criteria were detailed about the study, procedure, advantages and side effects.
- Informed written consent was obtained from all the patients.
- They were thoroughly investigated and assessed before surgery. For all patients, age, height and weight are noted.
- Patients shifted inside OR.
- Monitors were connected. All the vital parameters like Heart rate, Systolic Blood Pressure, Diastolic Blood Pressure, Mean Arterial Pressure were recorded pre operatively.
- Intravenous access obtained
- A standardized induction protocol was followed for all the patients which include Inj. Fentanyl (2µg/kg), Inj. Thiopentone Sodium (5mg/kg).
- Tracheal intubation was facilitated with Inj. Vecuronium (0.1mg/kg).
- After induction of anaesthesia, hemodynamic variables were recorded.
- After that, parts were prepared, painted and draped
 - **Group A** patients received Scalp Block with 0.25% Bupivacaine.
 - **Group B** patients received Pre-Incisional infiltration with 0.25% Bupivacaine with 1:4,00,000 Adrenaline.
- A Mayfield[™] head holder was used to stabilize the head during the surgery. At the time of pinning or anytime during procedure, if HR rises more than 10/min or MAP increased by more than 15mmHg over baseline values, attempts will be made to control the HR with by increasing Sevoflurane concentration. If HR or MAP remains higher, then Inj. Fentanyl at dose 0.5µg/kg was given.

- Anaesthesia was maintained with I MAC value of Sevoflurane in 30% O₂ & 70% N₂O. Patients were ventilated to obtain PaCO₂ values between 25-30mmHg.
- Mannitol (0.5-1g/Kg IV) was administered to avoid rise in ICP. Patients with Intracranial Tumours were also given 10mg of Dexamethasone IV.
- At the end of surgery, after adequate neuromuscular recovery, patient was reversed with Inj.Glycopyrrolate(0.005mg/kg) and Inj.Neostigmine (0.07mg/kg). Then Patients were extubated.
- Intraoperative vitals were recorded during several times including baseline, after induction, during Scalp Block/Local administration, 5 minutes after administration, skull pin insertion, skin incision, pericranial flap dissection, periosteal dissection, bone drilling, dural opening, brain dissection and manipulation, dural closure, bone closure, pericranial closure, skin closure and following extubation.
- Visual analogue scale(VAS) was explained to all patients. They were instructed to mark the severity of post operative pain in that scale.
- The primary outcome of the study was Assessment of intraop hemodynamics, post operative analgesia by VAS score.
- Secondary outcome was to assess intraoperative Opioid requirements & time for first rescue analgesia.
- The VAS scores, had been noted post operatively, after extubation then at half hourly interval for 6 hours and then till 24 hours. Initiation time of rescue analgesia in both the groups were also noted.

CALCULATION OF SAMPLE SIZE

The sample size was calculated based on a pilot study conducted at the institute. To detect a difference of MAP between the groups with 90% power at an *alpha value* of 0.05 and *beta value* of 0.01, a sample size was calculated as follows.

Description:

- The confidence level is estimated at 95%
- With a z value of 1.96
- The confidence interval or margin of error is estimated at +/-15
- Assuming that the sample will have the specified attribute p% =50 and q%=50

$$n = p\% \times q\% \times [z/e\%]^2$$

$$n = 50.4 \times 50 \times [1.96/15]^2$$

$$n = 42.68$$

Therefore 43 is the minimum sample size in each group required for the study

In our study we have taken 60 as the sample size with 30 in each group

STATISTICAL METHODS

Descriptive statistics was done for all data and suitable statistical tests of comparison were done. These included the mean and standard deviation (SD) for quantitative variables, and category frequency counts for qualitative variables. Next, inferential statistical analysis was undertaken.

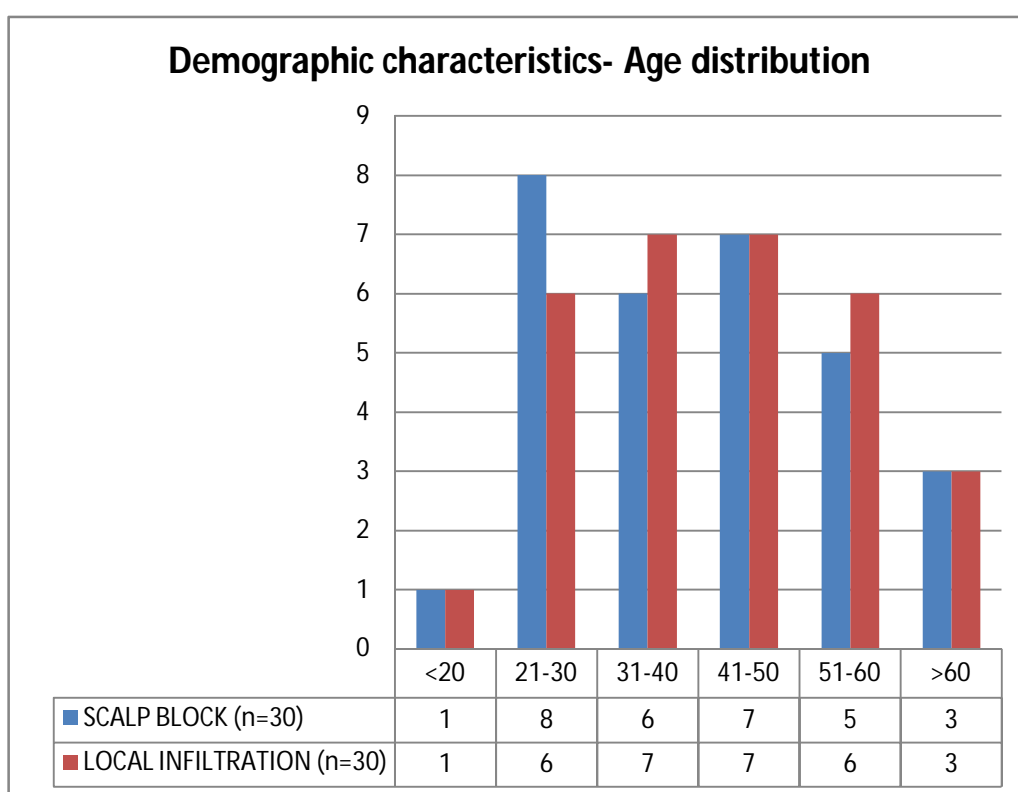
Continuous variables were analysed with the unpaired t-test and categorical variables were analysed with the Chi-Square Test with Yates correction. Alpha for significance for all inferences was set at $P < 0.05$. All tests of Hypotheses, wherever

applicable, were two-tailed. The data was analysed using SPSS(version 16.0-Copyright-2007)– value of less than 0.05 is taken as significant.

DEMOGRAPHIC PROFILES

The demographic profiles like age, sex, weight, height, BMI, ASA status were comparable between the two groups as discussed below

AGE

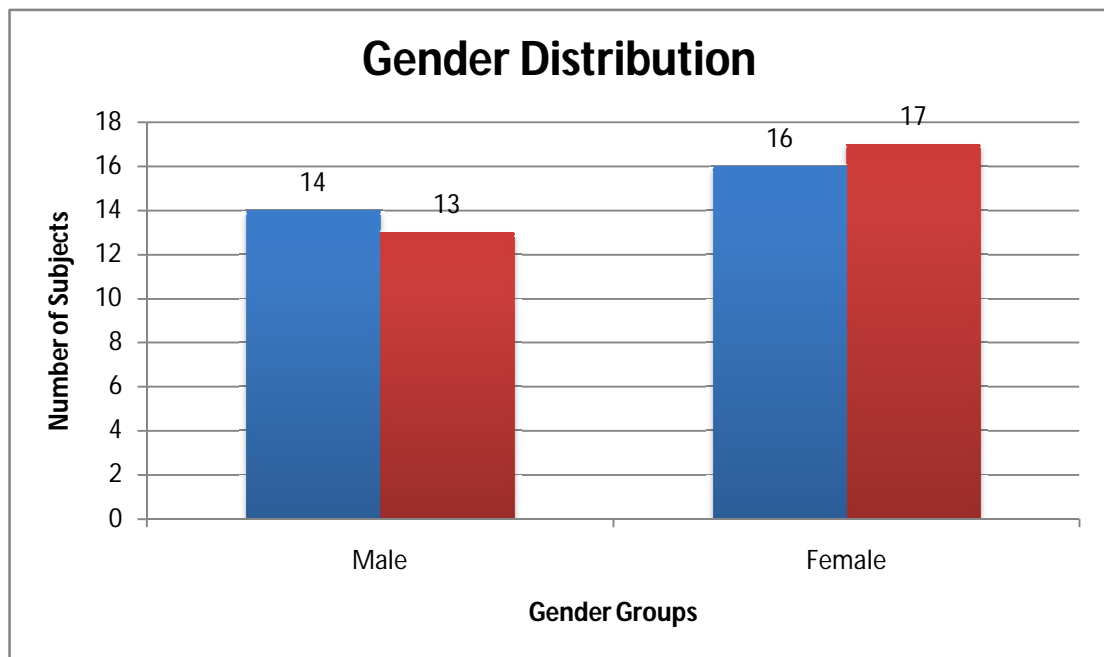


AGE DISTRIBUTION	SCALP BLOCK	LOCAL INFILTRATION
N	30	30
Mean	41.20	41.97
SD	13.90	13.59
P Value Independence t test		0.83

AGE DISTRIBUTION	SCALP BLOCK (N=30)	%	LOCAL INFILTRATION (N=30)	%
<20 Years	1	3.33%	1	3.33%
21-30 Years	8	26.7%	6	20%
31-40 Years	6	20%	7	23.3%
41-50 Years	7	23.3%	7	23.3%
51-60 Years	5	16.7%	6	20%
>60 Years	3	10%	3	10%

Most of the patients were clustered in the 41-50 years age group, 23.3% (n=7) in the SCALP Block Group and 23.3% (n=7) in the Local Infiltration Group. The mean age was 41.20 years in the SCALP Block Group and 41.97 years in the local Infiltration Group. By conventional criteria the association between the techniques *and age is considered to be not statistically significant* since $p > 0.05$.

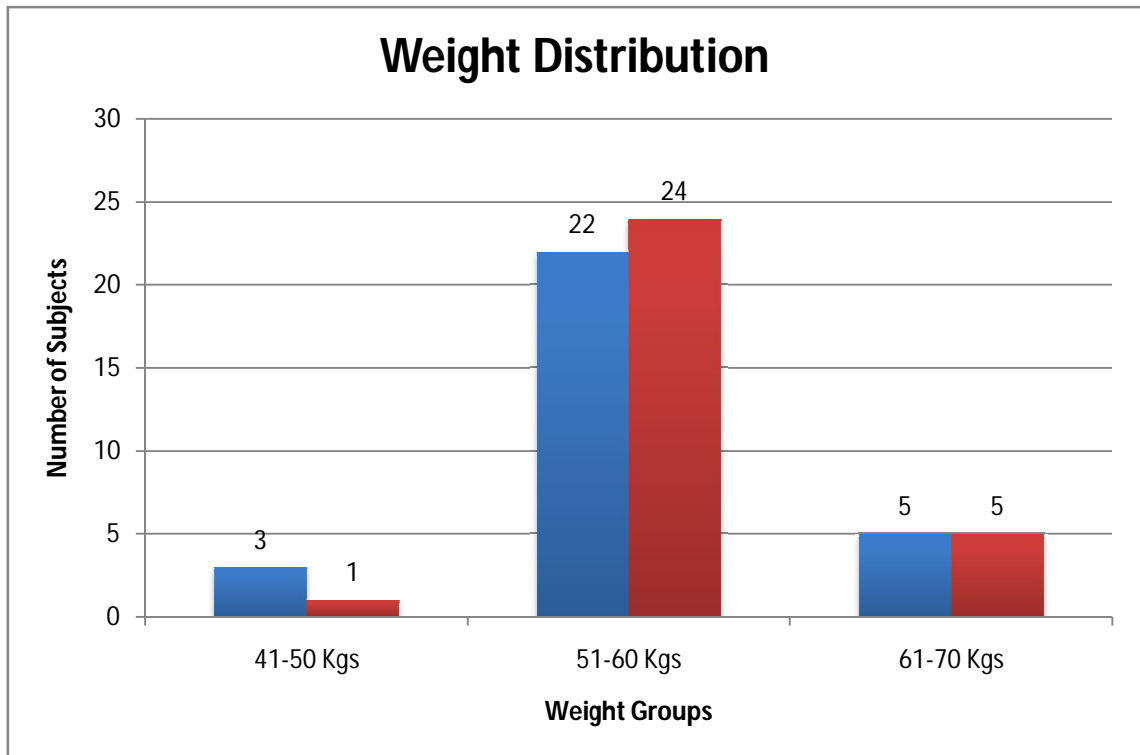
GENDER



GENDER DISTRIBUTION	SCALP BLOCK	%	LOCAL INFILTRATION	%
Male	14	46.67	13	43.33
Female	16	53.33	17	56.67
Total	30	100.00	30	100.00
P Value Chi-Square			1.00	

Males constituted 46.67% (n=14) of the SCALP Block Group and 43.33% (n=13) of the local Infiltration Group. By conventional criteria the association between the techniques and *gender is considered to be not statistically significant* since $p > 0.05$.

WEIGHT

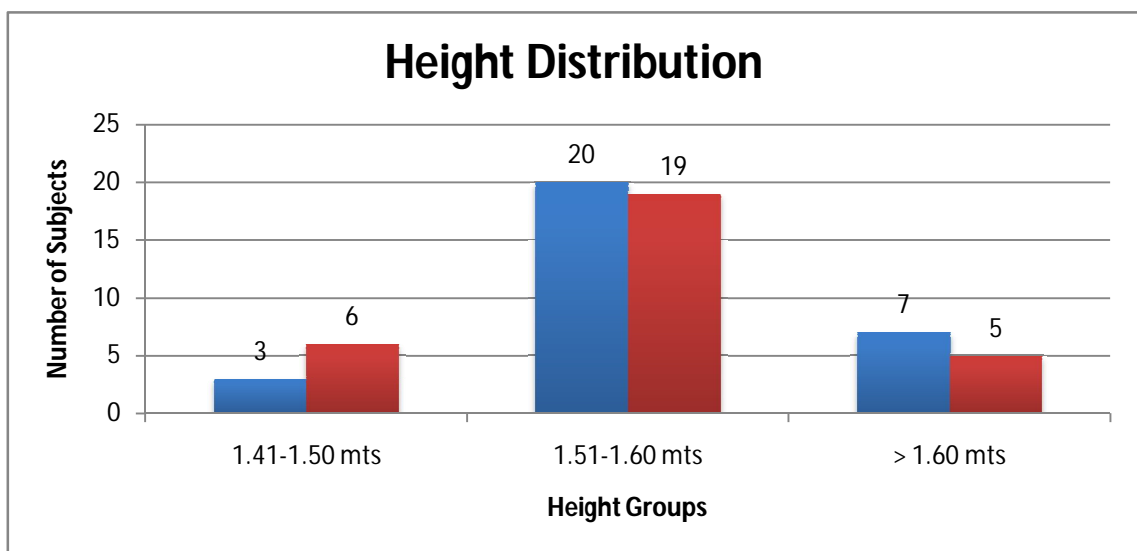


WEIGHT DISTRIBUTION	SCALP BLOCK	%	LOCAL INFILTRATION	%
41-50 Kg	3	10.00	1	3.33
51-60 Kg	22	73.33	24	80.00
61-70 Kg	5	16.67	5	16.67
Total	30	100.00	30	100.00

WEIGHT DISTRIBUTION	SCALP BLOCK	LOCAL INFILTRATION
N	30	30
Mean	55.57	59
SD	6.23	5.16
P Value Independence t test		0.06

Majority of the patients were clustered in the 51-60 Kg Weight group, 73.33% (n=22) in the SCALP Block Group and 80% (n=24) in the local Infiltration Group. The mean weight was 55.57 Kg in the SCALP Block Group and 59 Kg in the local Infiltration Group. By conventional criteria *the association between the techniques and weight is considered not to be statistically significant since $p > 0.05$.*

HEIGHT

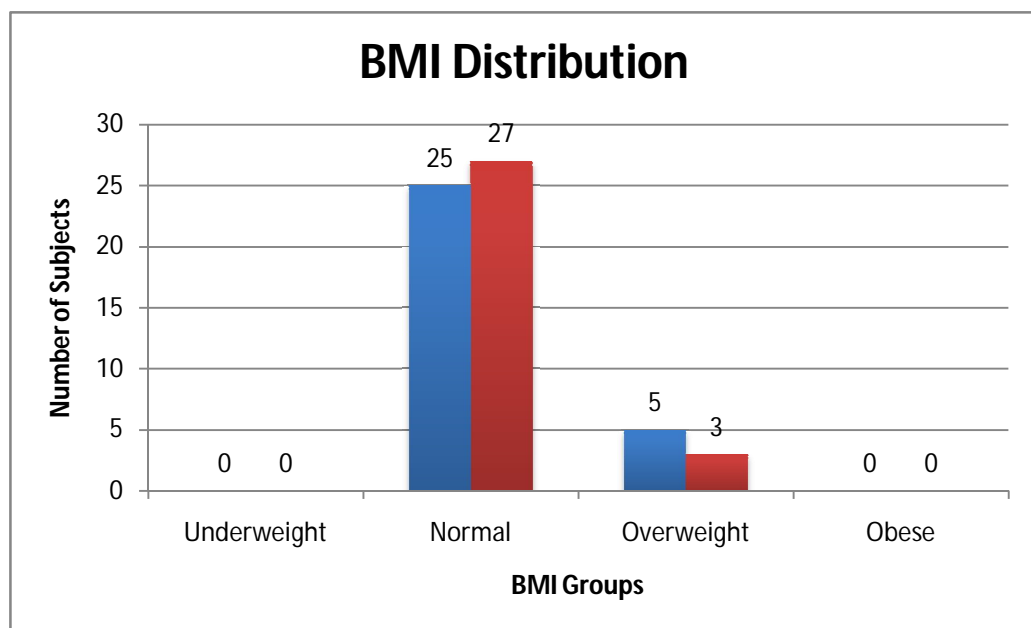


HEIGHT DISTRIBUTION	SCALP BLOCK	%	LOCAL INFILTRATION	%
1.41-1.50 m	3	10.00	6	20.00
1.51-1.60 m	20	66.67	19	63.33
> 1.60 m	7	23.33	5	16.66
Total	30	100.00	30	100.00

HEIGHT DISTRIBUTION	SCALP BLOCK	LOCAL INFILTRATION
N	30	30
Mean	1.55	1.57
SD	0.05	0.04
P Value Independence t test		0.15

Majority of the patients were clustered in the 1.51-1.60 mts Height group, 66.67% (n=20) in the SCALP Block Group and 63.33% (n=19) in the local Infiltration Group. The mean height was 1.55 metre in the SCALP Block Group and 1.57 metre in the local Infiltration Group. By conventional criteria *the association between the techniques and height is considered to be not statistically significant since $p > 0.05$.*

BODY MASS INDEX



BMI DISTRIBUTION	SCALP BLOCK	%	LOCAL INFILTRATION	%
Normal	25	83.33	27	90.00
Overweight	5	16.66	3	10.00
Total	30	100.00	30	100.00

BMI DISTRIBUTION	SCALP BLOCK	LOCAL INFILTRATION
N	30	30
Mean	23.05	23.95
SD	1.38	1.29
P Value Independence t test		0.06

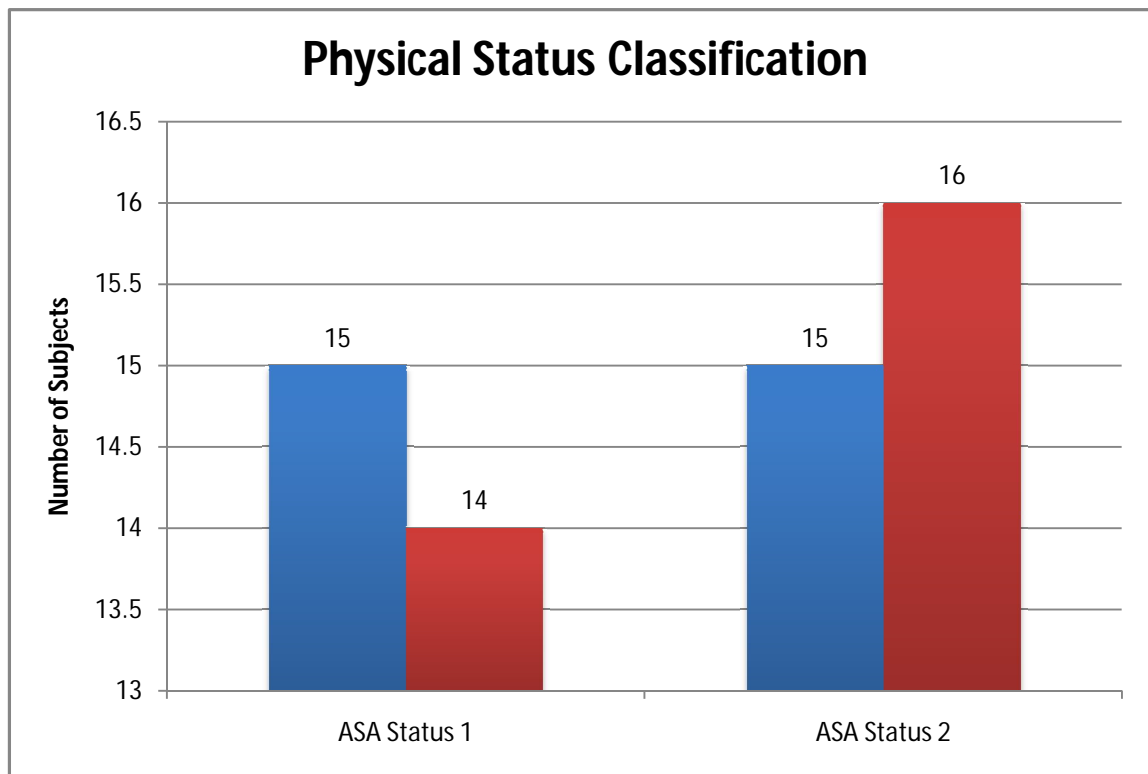
Majority of the patients were clustered in the Normal BMI group, 83.33% (n=25) in the SCALP Block Group and 90% (n=27) in the local Infiltration Group. The mean BMI was 23.05 in the SCALP Block Group and 23.95 in the local Infiltration Group. *By conventional criteria the association between the techniques and BMI is considered to be not statistically significant since $p > 0.05$.*

Since age, gender, height, weight and BMI are not statistically significant it means that there is no difference between the two groups. In other words, the two group contain subjects with the *same basic demographic characteristics*.

CONCLUSION

From the above data, it has been ascertained that there is no significant demographic differences between the two groups. Hence it ensures comparability between the two groups.

ASA-STATUS



	SCALP BLOCK	%	LOCAL INFILTRATION	%
ASA Status 1	15	50.00	14	46.67
ASA Status 2	15	50.00	16	53.33
Total	30	100.00	30	100.00
P Value Chi-Square Test			1.00	

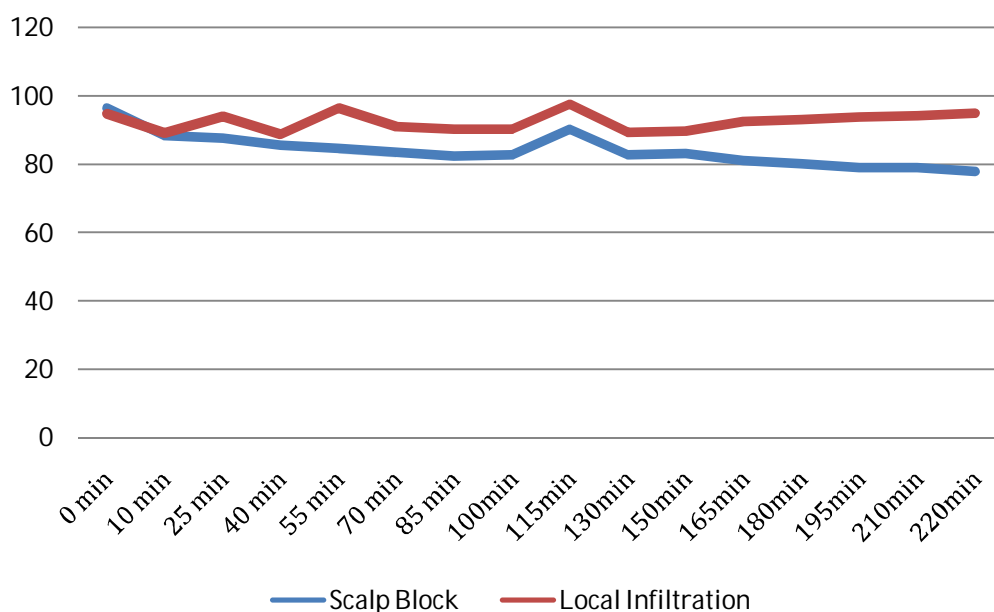
ASA Status 1 constituted 50.00% (n=15) of the SCALP Block Group and 46.67%(n=14) of the local Infiltration Group. By conventional criteria *the association between the techniques and physical status classification is considered to be not statistically significant since $p > 0.05$.*

HEART RATE

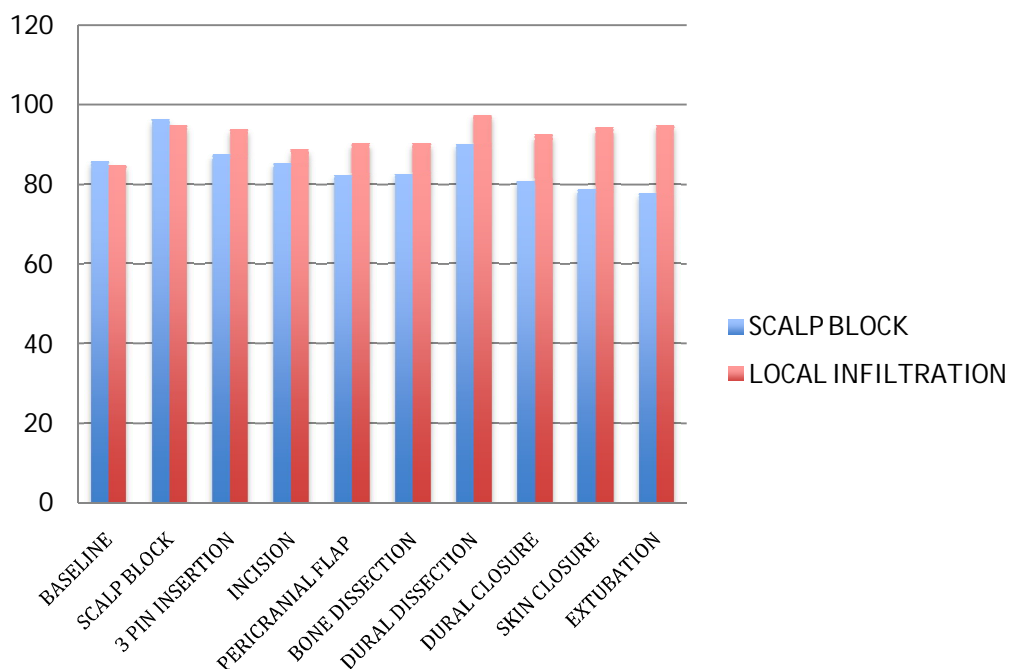
Heart Rate	EVENT	BASELINE	INDUCTION	SCALP BLOCK	10 MIN AFTER SCALP BLOCK	3 PIN INSERTION	INCISION	PERICRANIAL FLAP #1	PERICRANIAL FLAP #2	PERICRANIAL FLAP #3
TIME				0 min	10 min	25 min	40 min	55 min	70 min	85 min
SCALP	Mean	85.73	88.73	96.30	88.27	87.50	85.40	84.43	83.47	82.17
	SD	9.23	6.57	7.40	6.22	5.60	5.56	4.17	5.29	5.18
LOCAL	Mean	84.85	88.19	94.77	89.12	93.88	88.69	96.35	90.96	90.27
	SD	9.30	7.16	6.56	6.05	6.69	5.71	6.19	5.81	5.09
P VALUE		0.72	0.77	0.42	0.60	.002	0.06	.002	0.003	0.002

	EVENT	BONE DISSECTION	DURAL DISSECTION	BRAIN WORK #1	BRAIN WORK #2	DURAL CLOSURE	BONE CLOSURE	PERICRANIAL CLOSURE	SKIN CLOSURE	EXTUBATION
TIME		100 min	115 min	130 min	150 min	165 min	180 min	195 min	210 min	220 min
SCALP	Mean	82.70	90.10	82.70	82.97	80.93	80.07	78.90	78.83	77.77
	SD	5.59	4.99	5.64	5.15	4.88	4.71	5.47	4.79	4.29
LOCAL	Mean	90.27	97.50	89.19	89.58	92.38	93.08	993.73	94.19	94.85
	SD	4.96	5.37	4.49	3.91	3.14	3.72	3.95	4.52	3.83
P VALUE		0.002	0.001	0.002	0.003	0.002	0.002	0.001	0.003	0.002

Heart Rate Variation - Scalp Block vs. Local Infiltration



HEART RATE VARIATION



The mean Heart Rate at Baseline was 85.73 beats per minute in the SCALP Block Group and 84.85 beats per minute in the local Infiltration Group.

- By conventional criteria the association between the techniques and Heart Rate (Baseline and Intra Operative) is considered to be *statistically insignificant* since $p > 0.05$.
- The mean Heart Rate Intra Operatively varied from 77.77-96.30 beats per minute in the SCALP Block Group and 84.85 - 99.33 beats per minute in the local Infiltration Group.
- The mean Heart rate is 88.73 beats per minute in the SCALP Block Group compared to 88.19 in the local Infiltration Group following induction with a p-value of 0.77 according to Independence t-test
- The mean Heart rate is 96.30 beats per minute in the SCALP Block Group compared to 94.77 in the local Infiltration Group following Scalp block/Local Infiltration with a p-value of 0.42 according to Independence t-test
- The mean Heart rate is 88.27 beats per minute in the SCALP Block Group compared to 89.12 in the local Infiltration Group 10 mins following scalp block/Local administration with a p-value of 0.60 according to Independence t-test
- From the above data, it has been found that intraoperative heart rate between the two groups were *statistically insignificant* following induction ,scalp block/ Local administration, 10 mins following Scalp block/Local administration

Statistical Significance

- The mean Heart rate is 82.50 (difference of 1.77) beats per minute in the SCALP Block Group compared to 98.88 (difference of 9.03) Local Infiltration Group during 3 –pin insertion with a p-value of 0.002 according to Independence t-test
- The mean Heart rate is 85.40(difference of 0.17) beats per minute in the SCALP Block Group compared 88.69 (difference of 3.84)to the Local Infiltration Group at the time of incision a p-value of 0.06 according to Independence t-test and is *statistically insignificant*
- The mean Heart rate is decreased by 11.92 beats per minute in the SCALP Block Group compared to the Local Infiltration Group during pericranial flap dissection with a p-value of 0.04458according to Independence t-test
- The mean Heart rate is decreased by 7.57 beats per minute in the SCALP Block Group compared to the Local Infiltration Group during bone dissection with a p-value of 0.002 according to Independence t-test
- The mean Heart rate is decreased by 7.40 beats per minute in the SCALP Block Group compared to the Local Infiltration Group during dural dissection with a p-value of 0.001 according to Independence t-test
- The mean Heart rate is decreased by 11.45 beats per minute in the SCALP Block Group compared to the Local Infiltration Group during dural closure with a p-value of 0.002 according to Independence t-test
- The mean Heart rate is decreased by 13.01 beats per minute in the SCALP Block Group compared to the Local Infiltration Group during bone closure with a p-value of 0.002 according to Independence t-test

- The mean Heart rate is decreased by 15.47 beats per minute in the SCALP Block Group compared to the Local Infiltration Group during pericranial closure with a p-value of 0.001 according to dependence t-test
- The mean Heart rate is decreased by 15.36 beats per minute in the SCALP Block Group compared to the Local Infiltration Group during skin closure with a p-value of 0.003 according to Independence t-test
- This indicates that there is a true difference between the two groups and the difference is *statistically significant and has not occurred by chance*.

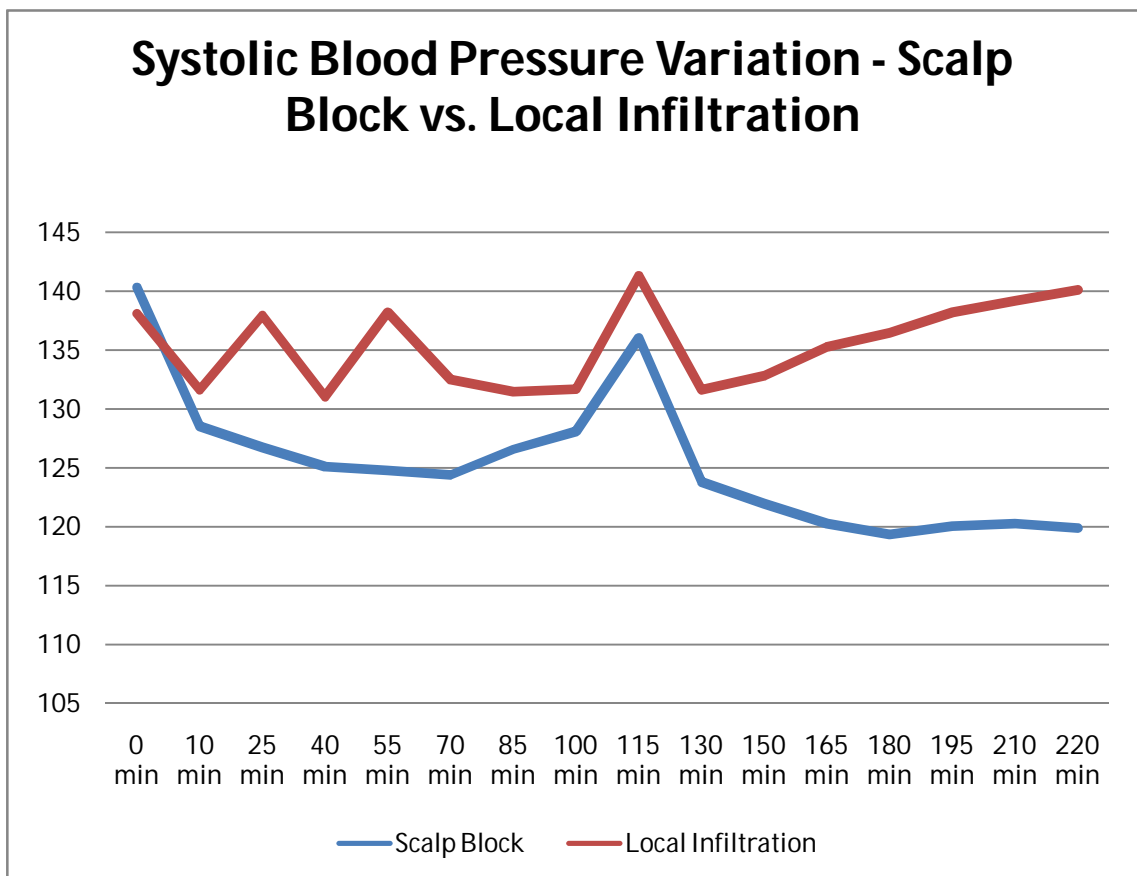
CONCLUSION

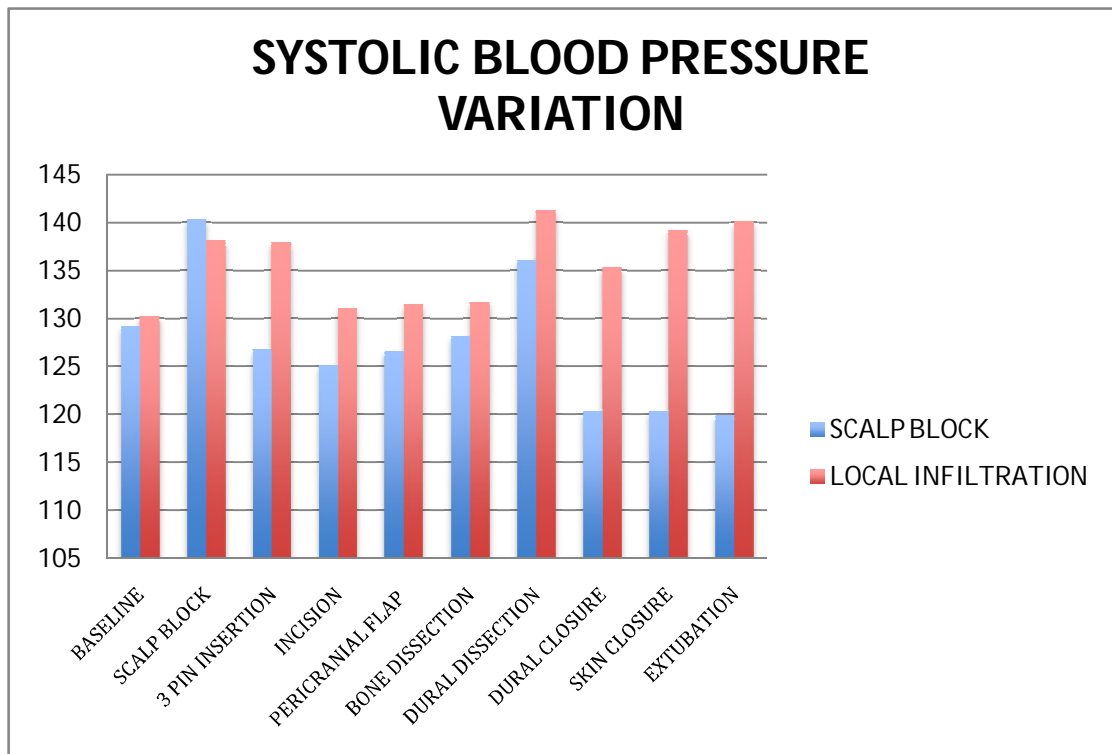
We conclude that SCALP Block resulted in a significant reduction in intra operative heart rates compared to local infiltration.

SYSTOLIC BLOOD PRESSURE

SBP	EVENT	BASELINE	INDUCTION	SCALOCK	10 MIN AFTER SCALP BLOCK	3-PIN INSERTION	INCISION	PERICRANIAL FLAP #1	PERICRANIAL FLAP #2	PERICRANIAL FLAP #3
TIME				0 min	10 min	25 min	40 min	55 min	70 min	85 min
SCALP	Mean	129.13	131.50	140.30	128.50	126.73	125.10	124.77	124.37	126.57
	SD	10.96	6.96	8.97	10.00	7.90	8.30	8.83	10.10	9.95
LOCAL	Mean	130.19	134.57	138.07	131.60	137.90	131.03	138.20	132.47	131.47
	SD	11	9.44	8.89	9.27	9.36	8.06	7.83	7.93	8.48
P VALUE		>0.99	0.62	0.34	0.66	0.003	.07	0.003	0.001	0.002

SBP	EVENT	BONE DISSECTION	DURAL DISSECTION	BRAIN WORK #1	BRAIN WORK #2	DURAL CLOSURE	BONE CLOSURE	PERICRANIA L CLOSURE	SKIN CLOSURE	EXTUBATION
TIME		100 min	115 min	130 min	150 min	165 min	180 min	195 min	210 min	220 min
SCALP	Mean	128.10	136.03	123.80	121.93	120.23	119.33	120.03	120.27	119.87
	SD	9.12	9.62	8.66	8.76	8.69	8.36	7.93	8.00	8.55
LOCAL	Mean	131.67	141.27	131.60	132.83	135.27	136.47	138.20	139.17	140.07
	SD	8.93	8.61	8.87	7.94	8.80	9.42	9.47	8.72	7.39
P VALUE		0.07	0.06	0.04	0.02	0.002	0.002	0.002	0.002	0.002





- The mean Systolic BP at Baseline was 129.13 mm Hg in the SCALP Block Group and 130.19 mm Hg in the Local Infiltration Group.
- By conventional criteria the association between the techniques and Systolic BP (Baseline and Intra Operative) is considered to be *statistically insignificant* since $p > 0.05$.
- The mean Systolic BP Intra Operatively varied from 119.33-140.30 mm Hg in the SCALP Block Group and 130.19-141.27 mm Hg in the Local Infiltration Group.
- The mean Systolic BP is 134.57 mmHg in the local infiltration Group compared to 131.50 in the SCALP Block Group following induction with a p-value of 0.62 according to Independence t-test

- The mean Systolic BP is 140.30 mmHg in the SCALP Block Group compared to 138.07 in the local Infiltration Group following Scalp block/Local Infiltration with a p-value of 0.34 according to Independence t-test
- The mean Systolic BP is 128.50mmHg in the SCALP Block Group compared to 131.60 in the local Infiltration Group 10 mins following scalp block/Local administration with a p-value of 0.66 according to Independence t-test
- From the above data, it has been found that intraoperative Systolic BP between the two groups were *statistically insignificant* following induction ,scalp block/ Local administration, 10 mins following Scalp block/Local administration

Statistical Significance

- The mean Systolic BP is decreased by 13 mmHg in the SCALP Block Group compared to Local Infiltration Group during 3 –pin insertion with a p-value of 0.003 according to Independence t-test
- The mean Systolic BP is decreased by 18 mmHg in the SCALP Block Group compared to the Local Infiltration Group during pericranial flap dissection with a p-value of 0.002 according to Independence t-test
- The mean Systolic BP is decreased by 3.57 mmHg in the SCALP Block Group compared to the Local Infiltration Group during bone dissection with a p-value of 0.07 according to Independence t-test and is *statistically insignificant*
- The mean Systolic BP is decreased by 5.18 mmHg in the SCALP Block Group compared to the Local Infiltration Group during dural dissection with a p-value of 0.06 according to Independence t-test and is *statistically insignificant*

- The mean Systolic BP is decreased by 15.04 mmHg in the SCALP Block Group compared to the Local Infiltration Group during dural closure with a p-value of 0.002 according to Independence t-test
- The mean Systolic BP is decreased by 17.14mmHg in the SCALP Block Group compared to the Local Infiltration Group during bone closure with a p-value of 0.002 according to Independence t-test
- The mean Systolic BP is decreased by 17.47mmHg in the SCALP Block Group compared to the Local Infiltration Group during pericranial closure with a p-value of 0.002 according to Independence t-test
- The mean Systolic BP is decreased by 18.9mmHg in the SCALP Block Group compared to the Local Infiltration Group during skin closure with a p-value of 0.002 according to Independence t-test
- This indicates that there is a true difference between the two groups and the difference is *statistically significant and has not occurred by chance*.

CONCLUSION

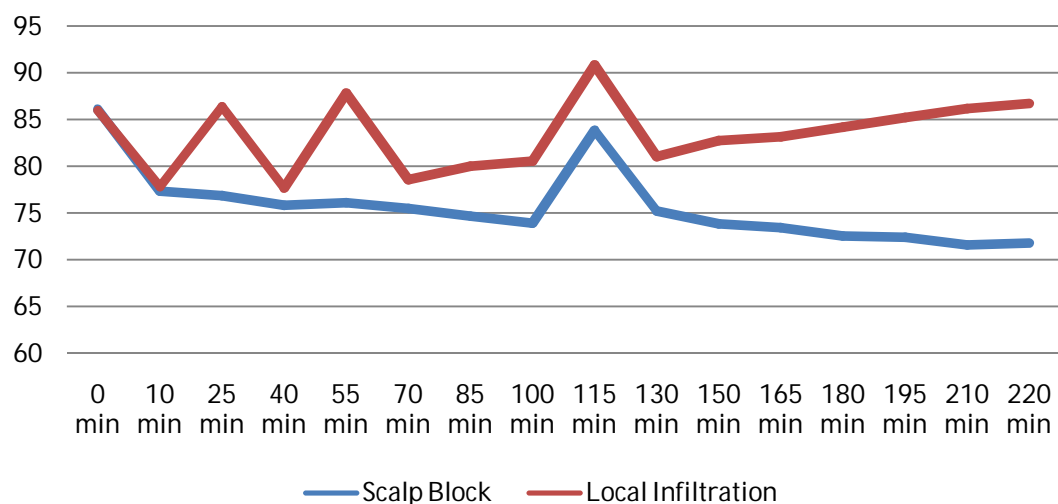
We conclude that SCALP Block resulted in a significant reduction in intra operative systolic blood pressure values compared to local infiltration. But there is no statistically significant variation of Systolic blood pressure values between two groups during incision, dural and bone dissection.

DIASTOLIC BLOOD PRESSURE

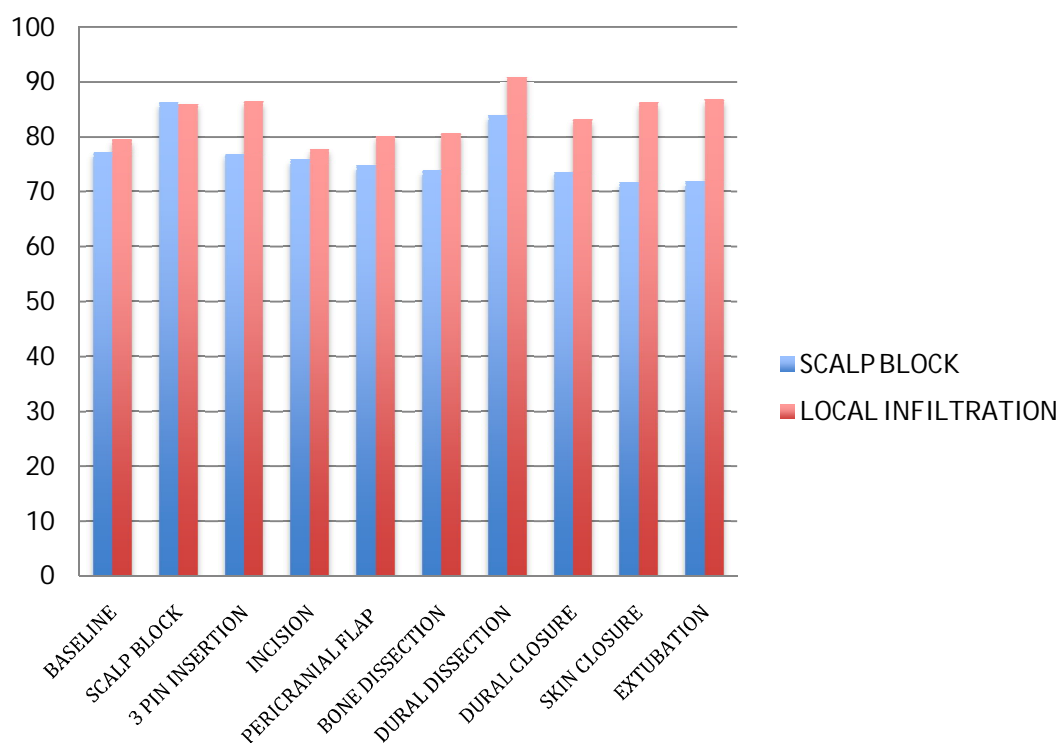
DIASTOLIC BLOOD PRESSURE	EVENT	BASELINE	INDUCTION	SCALP BLOCK	10 MIN AFTER SCALP BLOCK	3 PIN INSERTION	INCISION	PERICRANIAL FLAP #1	PERICRANIAL FLAP #2	PERICRANIAL FLAP #3
TIME				0 min	10 min	25 min	40 min	55 min	70 min	85 min
SCALP BLOCK	Mean	77.17	80.23	86.10	77.30	76.83	75.77	76.10	75.43	74.67
	SD	7.92	6.63	6.89	7.09	7.09	7.02	7.11	6.83	6.31
LOCAL INFILTRATION	Mean	79.34	78.67	85.97	77.80	86.33	77.67	87.77	78.57	80.00
	SD	8.00	6.39	7.04	7.21	6.54	6.66	6.29	6.75	6.05
P VALUE		>0.99	0.36	0.94	0.79	0.003	0.286	0.01	0.07	0.01

DIASTOLIC BLOOD PRESSURE	EVENT	BONE DISSECTION	DURAL DISSECTION	BRAIN WORK #1	BRAIN WORK #2	DURAL CLOSURE	BONE CLOSURE	PERICRANIAL CLOSURE	SKIN CLOSURE	EXTUBATION
TIME		100 min	115 min	130 min	150 min	165 min	180 min	195 min	210 min	220 min
SCALP BLOCK	Mean	73.87	83.83	75.17	73.83	73.43	72.53	72.37	71.57	71.77
	SD	7.43	7.07	7.24	7.39	7.24	7.75	8.15	7.31	7.45
LOCAL INFILTRATION	Mean	80.53	90.83	81.00	82.73	83.10	84.17	85.20	86.13	86.70
	SD	6.54	5.82	6.41	6.31	6.03	6.11	6.23	5.82	6.19
P VALUE		0.07	0.002	0.03	0.001	0.04	0.03	0.04	0.02	0.04

Diastolic Blood Pressure Variation - Scalp Block vs. Local Infiltration



DIASTOLIC BLOOD PRESSURE VARIATION



- The mean Diastolic BP at Baseline was 77.17 mm Hg in the SCALP Block Group and 79.34 mm Hg in the Local Infiltration Group.
- By conventional criteria the association between the techniques and Diastolic BP (Baseline and Intra Operative) is considered to be *statistically insignificant* since $p > 0.05$.
- The mean Diastolic BP Intra Operatively varied from 71.77-86.10 mm Hg in the SCALP Block Group and 77.80-90.83 mm Hg in the Local Infiltration Group.
- The mean Diastolic BP is 80.23 mmHg in the SCALP Block Group compared to 78.67 in the local Infiltration Group following induction with a p-value of 0.36 according to Independence t-test
- The mean Diastolic BP is 86.10 mmHg in the SCALP Block Group compared to 85.97 in the local Infiltration Group following Scalp block/Local Infiltration with a p-value of 0.94 according to Independence t-test
- The mean Diastolic BP is 77.30 mmHg in the SCALP Block Group compared to 77.80 in the local Infiltration Group 10 mins following scalp block/Local administration with a p-value of 0.79 according to Independence t-test
- From the above data, it has been found that intra-operative Diastolic BP between the two groups were *statistically insignificant* following induction ,scalp block/ Local administration, 10 mins following Scalp block/Local administration

Statistical Significance

- The mean Diastolic BP is decreased by 9.5 mmHg in the SCALP Block Group compared to Local Infiltration Group during 3 –pin insertion with a p-value of 0.003 according to Independence t-test
- The mean Diastolic BP is decreased by 11.67 mmHg in the SCALP Block Group compared to the Local Infiltration Group during pericranial flap dissection with a p-value of 0.01 according to Independence t-test
- The mean Diastolic BP is decreased by 3.57 mmHg in the SCALP Block Group compared to the Local Infiltration Group during bone dissection with a p-value of 0.07 according to Independence t-test and is *statistically insignificant*
- The mean Diastolic BP is decreased by 7 mmHg in the SCALP Block Group compared to the Local Infiltration Group during dural dissection with a p-value of 0.002 according to Independence t-test and is *statistically significant*
- The mean Diastolic BP is decreased by 9.67 mmHg in the SCALP Block Group compared to the Local Infiltration Group during dural closure with a p-value of 0.04 according to Independence t-test
- The mean Diastolic BP is decreased by 11.64mmHg in the SCALP Block Group compared to the Local Infiltration Group during bone closure with a p-value of 0.03 according to Independence t-test
- The mean Diastolic BP is decreased by 12.83mmHg in the SCALP Block Group compared to the Local Infiltration Group during pericranial closure with a p-value of 0.04 according to Independence t-test

- The mean Diastolic BP is decreased by 14.56mmHg in the SCALP Block Group compared to the Local Infiltration Group during skin closure with a p-value of 0.02 according to Independence t-test

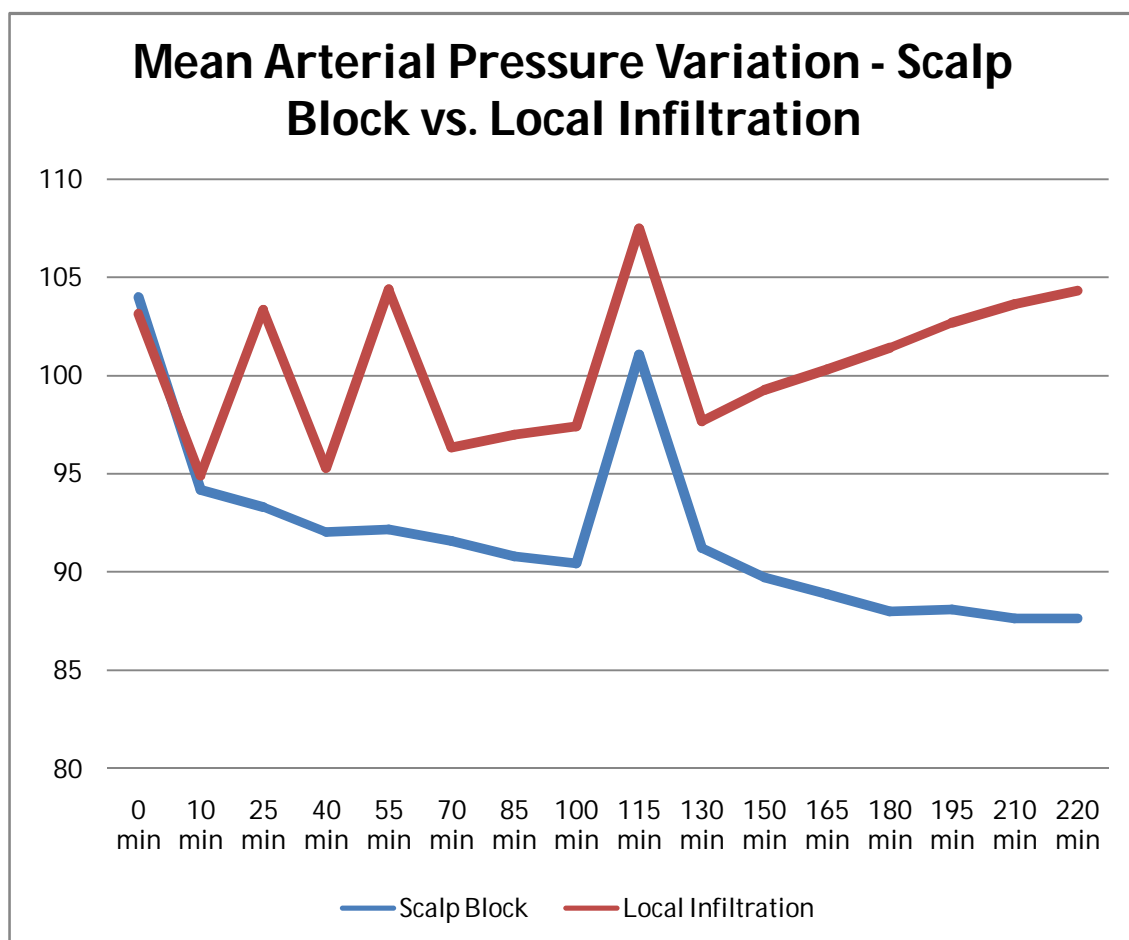
CONCLUSION

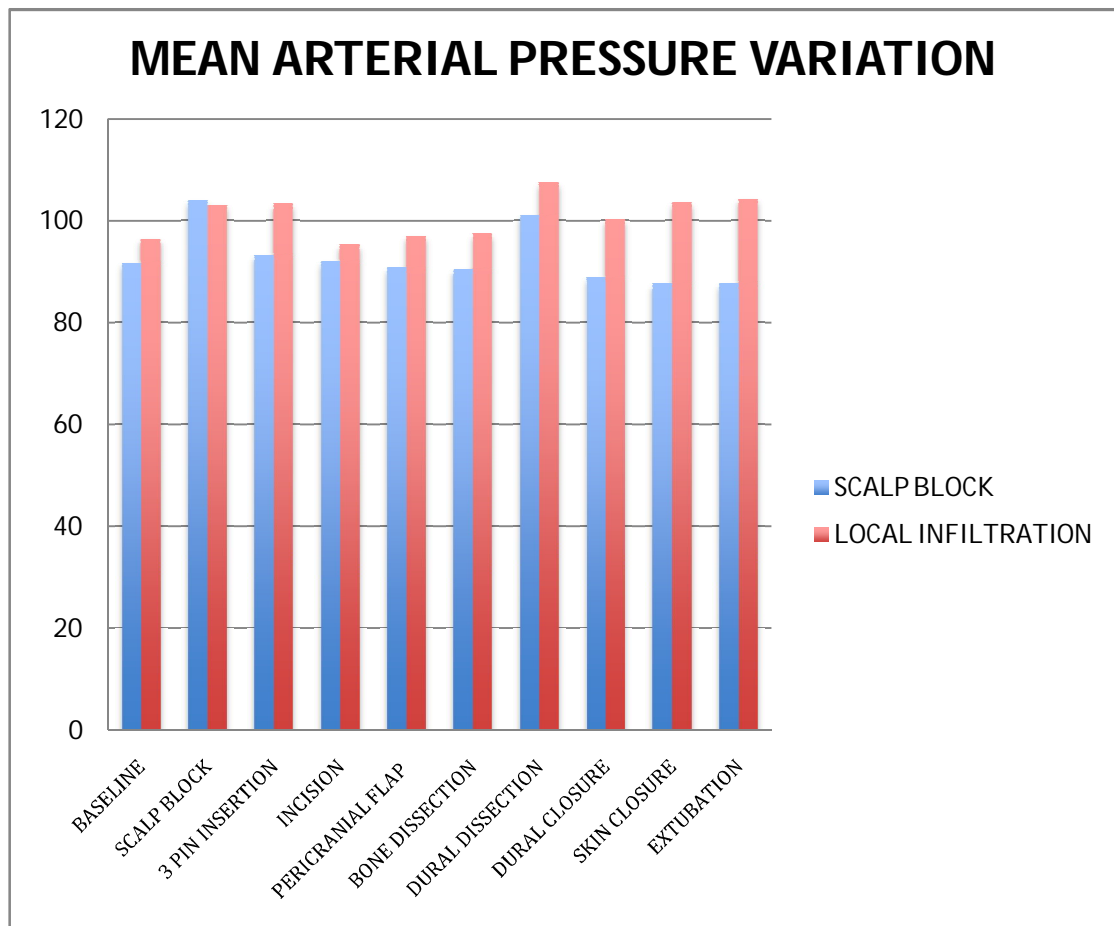
We conclude that SCALP Block resulted in a significant reduction in intra operative diastolic blood pressure values compared to local infiltration. But there is no statistically significant variation of Diastolic blood pressure values between two groups during incision, dural and bone dissection.

MEAN ARTERIAL PRESSURE

MEAN ARTERIAL PRESSURE	EVENT	BASELINE	INDUCTION	SCALP BLOCK	10 MIN AFTER SCALP BLOCK	3 PIN INSERTION	INCISION	PERICRANIAL FLAP #1	PERICRANIAL FLAP #2	PERICRANIAL FLAP #3
TIME				0 min	10 min	25 min	40 min	55 min	70 min	85 min
SCALP	Mean	91.70	97.15	103.99	94.19	93.30	92.04	92.16	91.58	90.80
	SD	7.37	5.65	6.80	6.85	6.49	6.56	6.81	6.66	6.44
LOCAL	Mean	96.51	95.79	103.15	94.89	103.35	95.28	104.40	96.35	96.98
	SD	5.98	5.79	7.01	7.05	6.45	6.19	5.83	6.36	6.14
P VALUE		0.36	0.36	0.65	0.69	0.04	0.07	0.06	0.04	0.04

MEAN ARTERI AL PRESSUR E	EVENT	BONE DISSECTION	DURAL DISSECTION	BRAIN WORK #1	BRAIN WORK #2	DURAL CLOSURE	BONE CLOSURE	PERICRANIAL CLOSURE	SKIN CLOSURE	EXTUBATION
TIME		100 min	115 min	130 min	150 min	165 min	180 min	195 min	210 min	220 min
SCALP	Mean	90.44	101.06	91.22	89.71	88.88	87.98	88.10	87.64	87.64
	SD	7.15	7.03	6.75	6.86	6.74	7.20	7.37	6.53	6.89
LOCAL	Mean	97.41	107.48	97.67	99.27	100.32	101.43	102.69	103.63	104.31
	SD	6.55	5.79	6.43	6.03	6.09	6.30	6.33	5.53	5.74
P VALUE		0.04	0.04	0.03	0.03	0.03	0.04	0.03	0.02	0.02





- The mean MAP at Baseline was 91.0 mm Hg in the SCALP Block Group and 96.51 mm Hg in the Local Infiltration Group.
- By conventional criteria the association between the techniques and MAP (Baseline and Intra Operative) is considered to be *statistically insignificant* since $p > 0.05$.
- The mean MAP Intra Operatively varied from 87.64-103.99 mm Hg in the SCALP Block Group and 94.89 - 104.31 mm Hg in the Local Infiltration Group.
- The mean MAP is 97.15 beats per minute in the SCALP Block Group compared to 95.79 in the local Infiltration Group following induction with a p-value of 0.36 according to Independence t-test

- The mean MAP is 103.99 beats per minute in the SCALP Block Group compared to 103.15 in the local Infiltration Group following Scalp block/Local Infiltration with a p-value of 0.65 according to Independence t-test
- The mean MAP is 94.19 beats per minute in the SCALP Block Group compared to 94.89 in the local Infiltration Group 10 mins following scalp block/Local administration with a p-value of 0.69 according to Independence t-test
- From the above data, it has been found that intraoperative MAP between the two groups were *statistically insignificant* following induction ,scalp block/Local administration, 10 mins following Scalp block/Local administration

Statistical Significance

- The mean MAP is decreased by 10.05 mmHg in the SCALP Block Group compared to Local Infiltration Group during 3 –pin insertion with a p-value of 0.04 according to Independence t-test
- The mean MAP is decreased by 12.24 mmHg in the SCALP Block Group compared to the Local Infiltration Group during pericranial flap dissection with a p-value of 0.04 according to Independence t-test
- The mean MAP is decreased by 4.57 mmHg in the SCALP Block Group compared to the Local Infiltration Group during bone dissection with a p-value of 0.04 according to Independence t-test
- The mean MAP is decreased by 4.18 mmHg in the SCALP Block Group compared to the Local Infiltration Group during dural dissection with a p-value of 0.04 according to Independence t-test

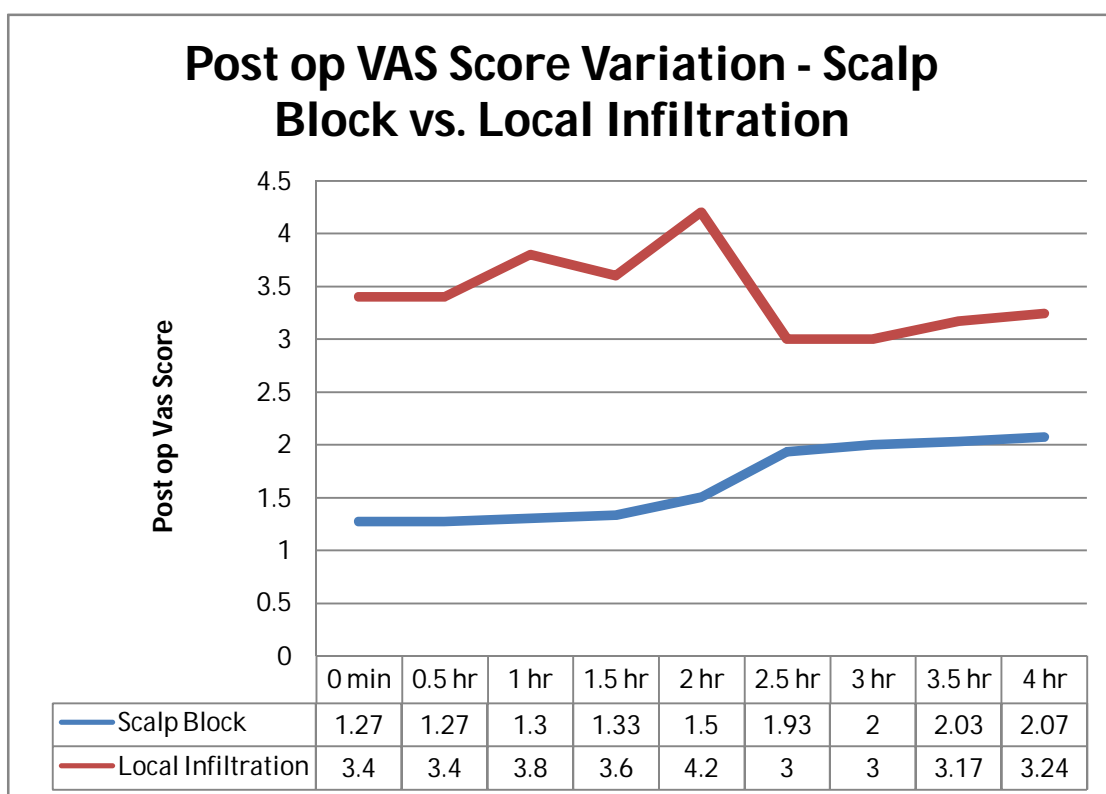
- The mean MAP is decreased by 11.44 mmHg in the SCALP Block Group compared to the Local Infiltration Group during dural closure with a p-value of 0.03 according to Independence t-test
- The mean MAP is decreased by 13.45mmHg in the SCALP Block Group compared to the Local Infiltration Group during bone closure with a p-value of 0.04 according to Independence t-test
- The mean MAP is decreased by 14.59mmHg in the SCALP Block Group compared to the Local Infiltration Group during pericranial closure with a p-value of 0.03 according to Independence t-test
- The mean MAP is decreased by 15.99mmHg in the SCALP Block Group compared to the Local Infiltration Group during skin closure with a p-value of 0.02 according to Independence t-test
- This indicates that there is a true difference between the two groups and the difference is *statistically significant and has not occurred by chance*.

CONCLUSION

We conclude that SCALP Block resulted in a significant reduction in intra operative MAP values compared to local infiltration. But there is no statistically significant variation of MAP values between two groups during incision, dural and bone dissection.

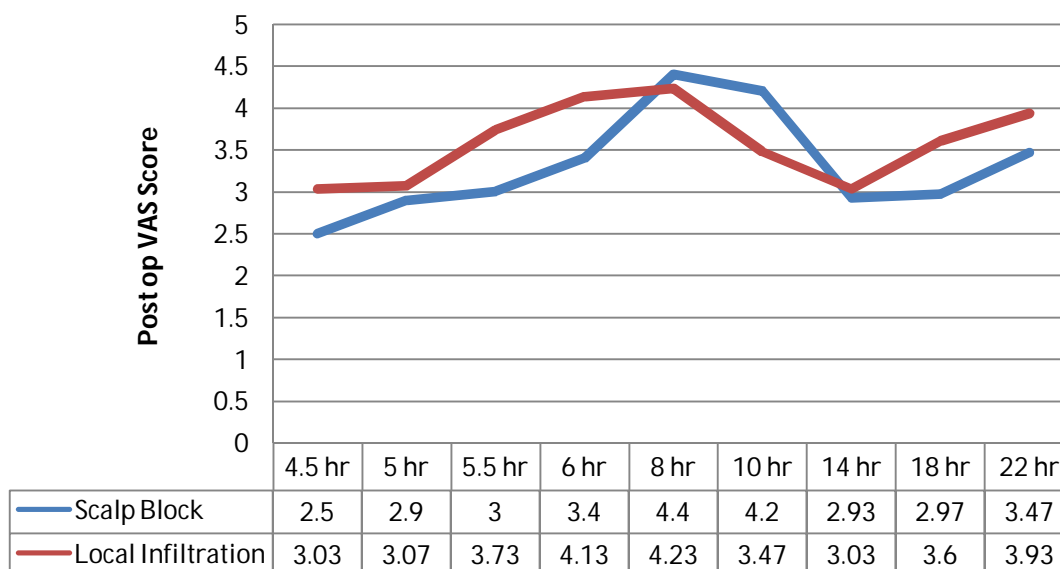
VISUAL ANALOG SCALE

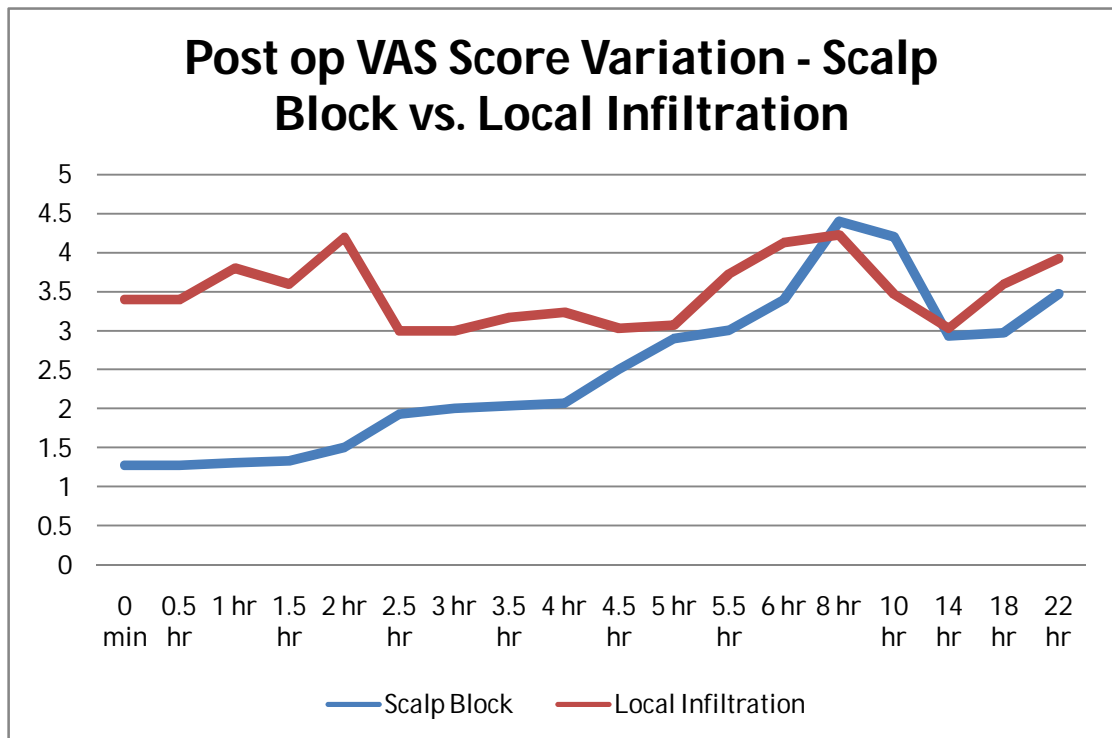
POST - OP VAS SCORE	TIME	0 min	0.5 hour	1 hour	1.5 hour	2 hour	2.5 hour	3 hour	3.5 hour	4 hour
SCALP BLOCK	Mean	1.27	1.27	1.30	1.33	1.50	1.93	2.0	2.03	2.07
	SD	0.45	0.45	0.47	0.48	0.51	0.25	0.56	0.18	0.25
LOCAL INFILTRATION	Mean	3.40	3.40	3.80	3.60	4.20	3.00	3.00	3.17	3.24
	SD	0.49	0.49	0.99	0.51	0.99	0.15	0.59	0.89	0.54
P VALUE		0.01	0.01	0.02	0.03	0.04	0.04		0.04	0.04



POST – OP VAS SCORE	TIME	4.5 hour	5 hour	5.5 hour	6 hour	8 hour	10 hour	14 hour	18 hour	22 hour
SCALP BLOCK	Mean	2.50	2.90	3.0	3.40	4.40	4.20	2.93	2.97	3.47
	SD	0.51	0.31	0.78	0.49	0.49	0.99	0.25	0.18	0.51
LOCAL INFILTRATION	Mean	3.03	3.07	3.73	4.13	4.23	3.47	3.03	3.60	3.93
	SD	0.18	0.25	0.45	0.63	0.86	0.86	0.18	0.49	0.25
P VALUE		0.003	0.02	0.02	0.02	0.36	0.07	0.08	0.09	0.07

Post op VAS Score Variation - Scalp Block vs. Local Infiltration





Statistical Significance

- The mean VAS is decreased by 2.13 in the SCALP Block Group compared to the Local Infiltration Group following extubation with a p-value of 0.01 according to Independence t-test
- The mean VAS is decreased by 2.10 in the SCALP Block Group compared to the Local Infiltration Group at 30th minute post-operatively with a p-value of 0.01 according to Independence t-test
- The mean VAS is decreased by 2.09 in the SCALP Block Group compared to the Local Infiltration Group at 1st hour post-operatively with a p-value of 0.02 according to Independence t-test
- The mean VAS is decreased by 2.27 in the SCALP Block Group compared to the Local Infiltration Group at 1.5 hour post-operatively with a p-value of 0.03 according to Independence t-test

- The mean VAS is decreased by 2.1 in the SCALP Block Group compared to the Local Infiltration Group at 2nd hour post-operatively with a p-value of 0.04 according to Independence t-test
- The mean VAS is decreased by 1.0 in the SCALP Block Group compared to the Local Infiltration Group at 2.5 hour post-operatively with a p-value of 0.04 according to Independence t-test
- The mean VAS is decreased by 1.04 in the SCALP Block Group compared to the Local Infiltration Group at 3rd hour post-operatively with a p-value of 0.04 according to Independence t-test
- The mean VAS is decreased by 1.14 in the SCALP Block Group compared to the Local Infiltration Group at 3.5 hour post-operatively with a p-value of 0.04188 according to Independence t-test
- The mean VAS is decreased by 1.17 in the SCALP Block Group compared to the Local Infiltration Group at 4th hour post-operatively with a p-value of 0.04 according to Independence t-test
- The mean VAS is decreased by 1.12 in the SCALP Block Group compared to the Local Infiltration Group at 4.5 hour post-operatively with a p-value of 0.03 according to Independence t-test
- The mean VAS is decreased by 1.05 in the SCALP Block Group compared to the Local Infiltration Group at 5th hour post-operatively with a p-value of 0.02 according to Independence t-test
- The mean VAS is decreased by 1.03 in the SCALP Block Group compared to the Local Infiltration Group at 5.5 hour post-operatively with a p-value of 0.04 according to Independence t-test

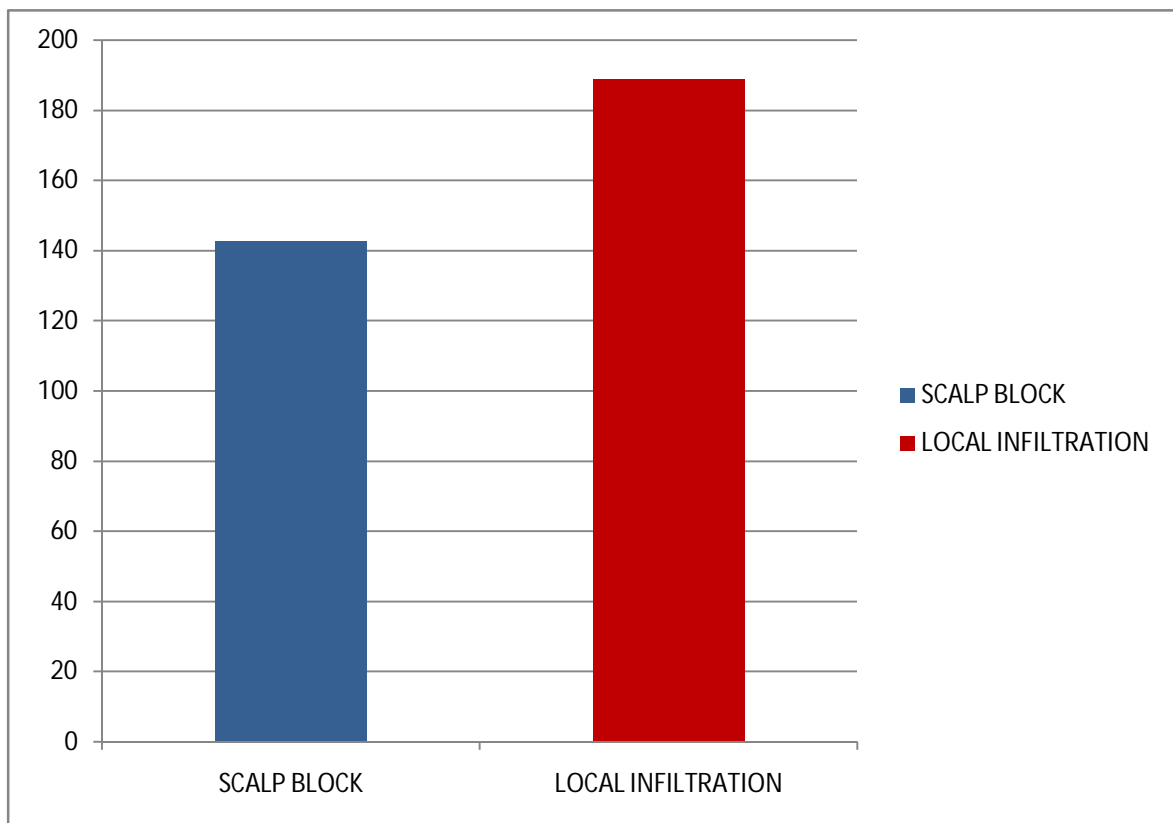
- The mean VAS is decreased by 0.96 in the SCALP Block Group compared to the Local Infiltration Group at 6th hour post-operatively with a p-value of 0.02 according to Independence t-test
- The mean VAS is decreased by 0.23 in the SCALP Block Group compared to the Local Infiltration Group at 8th hour post-operatively with a p-value of 0.36 according to Independence t-test and is *statistically insignificant*
- The mean VAS is decreased by 0.32 in the SCALP Block Group compared to the Local Infiltration Group at 10th hour post-operatively with a p-value of 0.07 according to Independence t-test and is *statistically insignificant*
- The mean VAS is decreased by 0.45 in the SCALP Block Group compared to the Local Infiltration Group at 14th hour post-operatively with a p-value of 0.08 according to Independence t-test and is *statistically insignificant*
- The mean VAS is decreased by 0.33 in the SCALP Block Group compared to the Local Infiltration Group at 18th hour post-operatively with a p-value of 0.09 according to Independence t-test and is *statistically insignificant*
- The mean VAS is decreased by 0.32 in the SCALP Block Group compared to the Local Infiltration Group at 22nd hour post-operatively with a p-value of 0.07 according to Independence t-test and is *statistically insignificant*

Conclusion

We conclude that SCALP Block resulted in a significant reduction in Visual Analog Score levels compared to local infiltration as far as *first 6 hours of early post operative period*. After that there were no statistically significant differences in VAS scores between the two groups.

INTRA-OPERATIVE OPIOID REQUIREMENT

GROUP	MEAN OPIOID REQUIREMENT (in µg/ml)	STANDARD DEVIATION
SCALP BLOCK	142.67	10.81
LOCAL INFILTRATION	188.67	15.25
P- Value	0.003	



The Anaesthesia protocol was standardized between the two groups with Inj.Fentanyl 2µg/kg as a pre-emptive analgesic. After that, variation in intra-operative hemodynamics was manipulated with increase in sevoflurane concentration. If no satisfactory response is obtained, then Inj.Fentanyl at the dose of 0.2µg/kg was given.

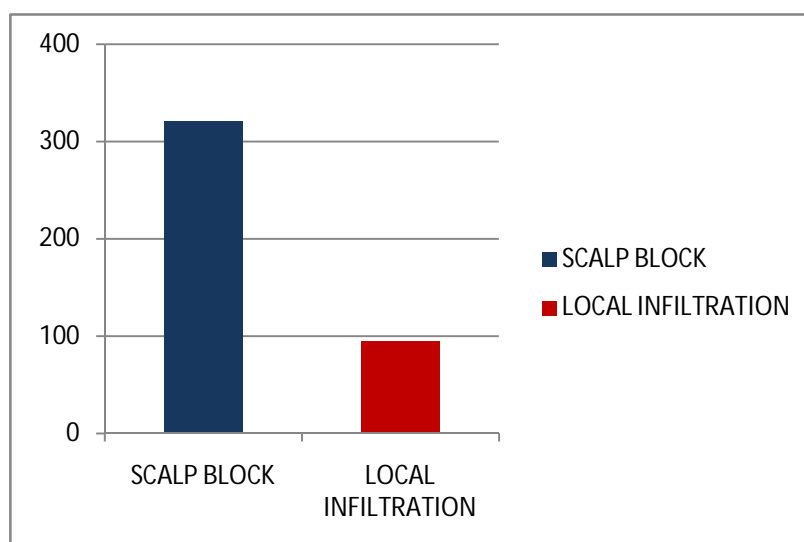
It has been found that mean Fentanyl requirement was 142.67 µg/kg in the Scalp group. But the mean requirement in local infiltration group was about 188.67 µg/kg. Hence , Scalp block has significantly reduced the intra-operative opioid requirements when compared with the local infiltration group.

CONCLUSION:

We conclude that there is statistically significant reduction in intra-operative opioid requirement since the P-value is <0.05

DURATION OF POST-OP ANALGESIA

GROUP	MEAN DUARTION OF ANALGESIA (minutes)	STANDARD DEVIATION
SCALP BLOCK	320.34	30.81
LOCAL INFILTRATION	94.67	22.25
P- Value	0.003	



The mean duration of post-operative analgesia in Scalp block group was 320.34 minutes with standard deviation of 30.81. Whereas, the mean duration of

analgesia in Local infiltration group was found to be 94.67 minutes with standard deviation of 22.25.

Hence, there is statistically significant increase in duration of post operative analgesia in Scalp block group when compared to the Local infiltration group since P-value is <0.05

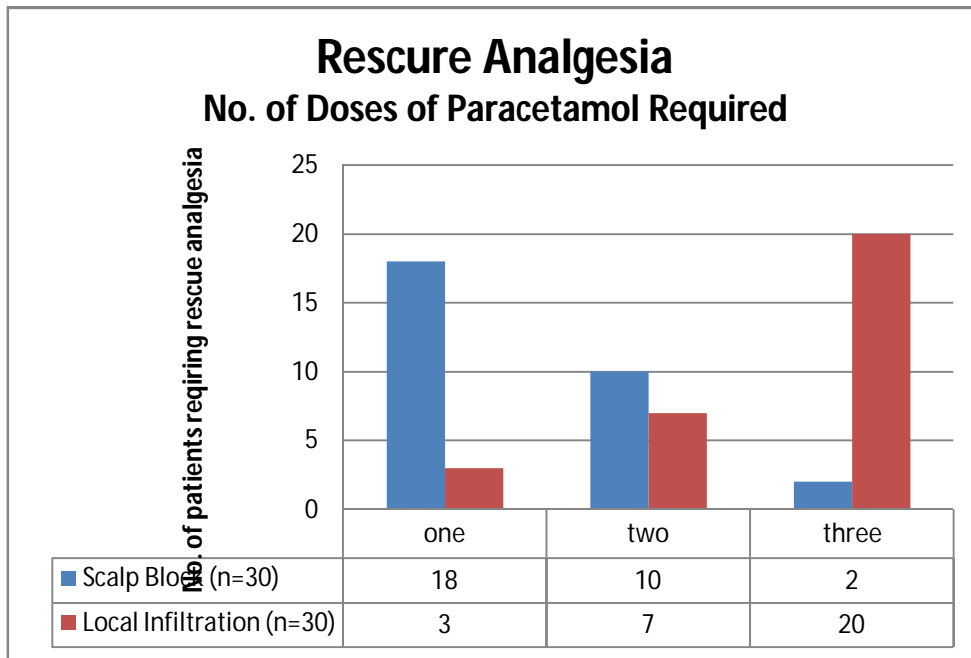
RESCUE ANALGESIA

From the observation it has been found that , only 6.67%(n=2) in the scalp Block required rescue analgesic in the first 6 hours. On the other hand,73.33% in the Local Infiltration required rescue analgesic within the first 6 hours.

Between 6-8 hours, 20% of patients in the Scalp Block group required rescue analgesic. In the other group about 16.67% required rescue in 6-8 hours.

After 8 hours ,there is no much difference in the requirement of rescue analgesics between the two groups.

NUMBER OF DOSES OF INJECTION IV PARACETAMOL	SCALP BLOCK	%	LOCAL INFILTRATION	%
1	18	60	3	10
2	10	33.33	7	23.33
3	2	6.66	20	66.66



From the observed parameters, it has been found that 66.67% (n=20) patients in the local infiltration required 3 doses of rescue analgesics in 24 hours. On contrary, only 6.67% (n=2) patients in the scalp block had required three doses of rescue analgesia.

Also, about 60% patients in the scalp block group required only one rescue analgesia in 24 hours. On the other hand, only 10% of patients in the local infiltration have obtained satisfactory analgesia with single rescue analgesic dose.

Clinical Significance

- The increase in Mean time for first dose of injection Paracetamol is more in the SCALP Block Group compared to the Local Infiltration Group
- Also the total number of rescue analgesics required in the Scalp block is less when compared with the local infiltration group in 24 hours.

CONCLUSION

We conclude that SCALP Block resulted in a significant increase in mean time required for first dose of injection Paracetamol compared to local infiltration.

DISCUSSION

This prospective, randomized, double blinded controlled study is to assess and compare the analgesic analgesic efficacy of Scalp block with 0.25% Bupivacaine vs Pre Incisional Local infiltration with 0.25% Bupivacaine with Adrenaline(1:400,000) in patients undergoing Elective Craniotomies in Rajiv Gandhi Government General hospital – Madras Medical College.

Sixty patients belonging to ASA1 and 2, between 18 to 65 years of either sex, satisfying inclusion criteria were randomized into two groups containing 30 patients each.

- **Group A** patients received Scalp Block with 0.25% Bupivacaine.
- **Group B** patients received Pre-Incisional infiltration with 0.25% Bupivacaine with 1:4,00,000 Adrenaline

In my study, it has been found that Scalp Block with 0.25% Bupivacaine was associated with stable intraoperative hemodynamics during skull pinning when compared with the local infiltration group.

These results are correlating with the study mentioned as follows.

1. *Pinosky ,Mark et al⁽³⁵⁾ conducted a study to assess the effect of Scalp Block with 0.25% bupivacaine on hemodynamic responses like systolic blood pressure(SBP), diastolic blood pressure(DBP) and mean arterial pressure(MAP) during 5 mins after induction during pinning and 3 mins after pinning.They have observed that scalp block with 0.25% Bupivacaine blunts the hemodynamic response to skull pinning. There were no additional requirements of opioids or end tidal Isoflurane in scalp block group*
2. *Rubial M et al⁽³⁷⁾, compared the efficiency of scalp block on attenuating the hemodynamic response with regard to skull pin placement. They have*

observed that hemodynamic responses were higher in group that have received opioids than in group that have received scalp block with local anaesthetic agents. They also found that hemodynamic response in scalp block group was comparatively lesser than that of local infiltration group.

3. *Geze et al ^[20] compared the effect of scalp block & local infiltration on hemodynamics during skull pin placement. Responses monitored were HR,SBP,DBP,Serum Cortisol and ACTH before and after skull pin placement. They have found out that all the above mentioned variables were significantly lower in scalp block group. Hence they concluded that scalp block was effective in attenuating hemodynamic response and stress response to skull pin placement when compared to local infiltration*

In my study it has been found that,

- SCALP Block resulted in a significant reduction in intra operative heart rates compared to local infiltration during pericranial flap dissection, dural incision, bone dissection as well as during dural,bone and skin closure
- SCALP Block resulted in a significant reduction in intra operative systolic blood pressure values compared to local infiltration during pericranial flap dissection, dural incision, bone dissection as well as during dural,bone and skin closure
- SCALP Block resulted in a significant reduction in intra operative diastolic blood pressure values compared to local infiltration. during pericranial flap dissection, dural incision, bone dissection as well as during dural,bone and skin closure

- SCALP Block resulted in a significant reduction in intra operative MAP values compared to local infiltration during pericranial flap dissection, dural incision, bone dissection as well as during dural, bone and skin closure

These results are in correlation with the following study as mentioned below

1. *Bloomfield et al ^[9], conducted study on the effect of scalp block on intra operative hemodynamics. HR, SBP,DBP,MAP were compared . They were compared after induction, during scalp infiltration and during dural and skin closure..It has been found that scalp block with Bupivacaine was effective in blunting hemodynamic responses during pin placement and skin incision*
2. *Lawan Tuchida et al ^[27], conducted study to found out the efficacy of scalp block with 0.25% Bupivacaine on intraoperative hemodynamics comparing with scalp block with 0.9% NACL. They concluded that Scalp block with 0.25% Bupivacaine reduces rise in HR & MAP in response to noxious stimulation*

In my study, it has been found that

SCALP Block resulted in a significant reduction in Visual Analog Score levels compared to local infiltration as far as first 6 hours of early post operative period.

These results are in correlation with the following study as mentioned below.

- *Bala et al^[5], assessed the efficiency of Scalp block with 0.5% Bupivacaine in Craniotomy patients on post operative pain relief. They have found out that 60% patients in placebo group experienced moderate to severe pain as compared to 25% patients in Scalp block group. Median pain scores upto 6 hours were significantly lower in Scalp Block group.*

Number of doses of rescue analgesic is also lower in Scalp Block group. They have concluded that Scalp Block using 0.5% Bupivacaine significantly reduce the severity of pain in patients undergoing craniotomy.

Further, it has been found that the mean Fentanyl requirements were 142.67µg/kg in the SCALP Block group when compared with 188.67µg/kg in the Local infiltration groups. Hence, Local infiltration group requires 1µg/kg of Inj.Fentanyl higher than that of Scalp Block group.

These results are in correlation with the following study as mentioned below

- *Lawan Tuchida et al ^[27], conducted study to found out the efficacy of scalp block with 0.25% Bupivacaine on intraoperative opioid requirements. They have found that Scalp block group requires less intraoperative Inj.Fentanyl when compared with the control group.*

The mean *duration of post-operative analgesia* in Scalp block group was **320.34 minutes** Whereas, the mean duration of analgesia in Local infiltration group was found to be **94.67**

Hence, *there is statistically significant increase in duration of post operative analgesia in Scalp block group when compared to the Local infiltration group*

In my study it has been found that, SCALP Block resulted in a significant increase in mean time required for first dose of injection Paracetamol compared to local infiltration.

These results are in correlation with the following study as mentioned below

- *Biswas et al ^[7], have conducted a placebo controlled, prospective ,randomized double blind study. They have evaluated the efficacy of Pre-Incisional Scalp block with 0.25% Bupivacaine on post operative analgesic requirements and*

also in post operative pain perception. They have found that Scalp block with 0.25% Bupivacaine delayed the need of rescue analgesic till 480 mins when compared with 30 mins in placebo group. They concluded that Bupivacaine delayed the requirement of the first dose of the rescue analgesic in their study.

Postoperative drowsiness, postoperative complications like nausea and vomiting, was increased in patients who were given local infiltration group corroborating with the increase in Inj.Fentanyl requirements in Local Infiltration group.

These results are in correlation with the following study as mentioned below

- *Hansen et al,⁽²¹⁾ conducted a systemic review on post craniotomy pain relief. Four treatment modalities and a total of 519 patients & nine RCTS were compared. They concluded that Scalp block with local anaesthetic agents produces pain relief for about 6 hours of immediate post operative period. And the incidence of nausea and vomiting is much lesser when compared with other groups*

LIMITATIONS OF THE STUDY

- Only ASA I and ASA II patients were included.
- No patients with Glasgow ComaScale(GCS) below 15 were included in the study
- Direct estimation of ICP was not attempted. Only the hemodynamic responses were noted
- No placebo group included to highlight the differences in the hemodynamic responses, since both the groups have been proven superior to placebo in different studies.

SUMMARY

To summarize, on performing the double blinded prospective randomized controlled trial comparing the analgesic efficacy of Scalp block with 0.25% Bupivacaine vs pre incisional wound infiltration with 0.25% Bupivacaine with adrenaline(1:400,000) in patients undergoing elective craniotomies, the following observations were made,

- There were significant differences in intra-operative hemodynamics between the two groups. Scalp Block resulted in statistically significant reduction in Heart Rate, Systolic Blood Pressure, Diastolic Blood Pressure and Mean Arterial Pressure
- There was increased duration of Post Operative analgesia in Scalp Block group when compared with the local infiltration group.
- The opioid requirement in the intra-operative period was significantly lesser in Scalp Block group when compared with the local infiltration group.
- Requirement of rescue analgesic is significantly lesser during early post operative period (Upto 8 hours) in the Scalp Block group when compared with Local infiltration group

CONCLUSION

In conclusion, Scalp block with 0.25% Bupivacaine is effective and superior to Pre-Incisional Local infiltration with 0.25% Bupivacaine with 1:4,00,000 Adrenaline in attenuating hemodynamic responses to noxious stimuli. Scalp block also provides increased duration of post operative analgesia when compared with local infiltration. Scalp Block also results in significant reduction in intraoperative opioids and post operative rescue analgesic requirements.

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INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE, CHENNAI-3

EC Reg No.ECR/270/Inst./TN/2013
Telephone No. 044 25305301
Fax : 044 25363970

CERTIFICATE OF APPROVAL

To
Dr.R.Balaji
Postgraduate M.D.(Anaesthesiology)
Madras Medical College
Chennai 600 003

Dear Dr.R.Balaji,

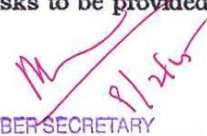
The Institutional Ethics Committee has considered your request and approved your study titled **"A prospective randomized study comparing the analgesic efficacy of scalp block with 0.25% Bupivacaine Vs pre incisional local infiltration with 0.25% Bupivacaine with Adrenalline (1:400,000) in patients undergoing Elective Craniotomies" No.05022015.**

The following members of Ethics Committee were present in the meeting held on 03.02.2015 conducted at Madras Medical College, Chennai-3.

- | | |
|--|----------------------|
| 1. Dr.C.Rajendran, M.D., | : Chairperson |
| 2. Dr.R.Vimala, M.D., Dean, MMC, Ch-3 | : Deputy Chairperson |
| 3. Dr.B.Kalaiselvi, M.D., Vice-Principal, MMC, Ch-3 | : Member Secretary |
| 4. Dr.R.Nandini, M.D., Inst.of Pharmacology, MMC | : Member |
| 5. Dr.P.Ragumani, M.S., Professor, Inst.of Surgery, MMC | : Member |
| 6. Dr.Md.Ali, M.D., D.M., Prof. & HOD of Medi.G.E., MMC | : Member |
| 7. Dr.K.Ramadevi, Director, Inst.of Biochemistry, MMC | : Member |
| 8. Dr.Saraswathy, M.D., Director, Pathology, MMC, Ch-3 | : Member |
| 9. Dr.S.G.Sivachidambaram, M.D., Director i/c
Institute of Internal Medicine, MMC, Ch-3 | : Member |
| 10. Thiru S.Rameshkumar | : Lay Person |
| 11. Thiru S.Govindasamy, B.A., B.L., | : Lawyer |
| 12. Tmt.Arnold Saulina, M.A., MSW., | : Social Scientist |

We approve the proposal to be conducted in its presented form.

The Institutional Ethics Committee expects to be informed about the progress of the study and SAE occurring in the course of the study, any changes in the protocol and patients information/informed consent and asks to be provided a copy of the final report.


MEMBER SECRETARY
Member Secretary, Ethics Committee
MADRAS MEDICAL COLLEGE
CHENNAI-600 003

ஆராய்ச்சி தகவல் தாள்

ஆராய்ச்சி தலைப்பு

மண்டை ஓடு பிளவு அறுவை சிகிச்சையின்போது .25% புபிவெகெயின் மருந்துக் கலவையை உச்சிவட்டக் குடுமித் தோல் நரம்புகளுக்கு இடையே செலுத்துவது மற்றும் 0.25% புபிவெகெயின் மற்றும் 1:4,00,000 அடரினலின் கலவையை அறுவை சிகிச்சை செய்யும் இடத்தில் நேரடியாக செலுத்துவதால் ஏற்படும் வலி நிவாரணத்தையும் ஒப்பிடும் ஆய்வு

ஆராய்ச்சியாளர் பெயர் : மருத்துவர்.இரா.பாலாஜி

பங்கேற்பாளர் பெயர் :

ஆராய்ச்சியின் நோக்கம்

இவ்வாய்வு கீழ்க்கண்ட கோணங்களின் ஒப்பிடப்படுகிறது.

- 1) அறுவை சிகிச்சையின்போதும் ஏற்படும் நாடித்துடிப்பு மற்றும் இரத்த அழுத்த மாற்றங்கள்
- 2) அறுவை சிகிச்சைப்பின்னர் ஏற்படும் வலி நிவாரணத்தின் அளவு கணக்கிடப்படுகிறது.

ஆய்வு முறை

ஆய்வில் பங்குபெறும் நோயாளிகள் இரண்டு குழுக்களாகப் பிரிக்கப்படுவர்.

- குழு-1 0.25% புபிவெகெயின் மருந்து கலவையை உச்சிவட்டக் குடுமித் தோல் நரம்புகளுக்கிடையே செலுத்தப்படும்.
- குழு-2 0.25% புபிவெகெயின் மற்றும் 1:4,00,000 அடரினலின் மருந்து கலவை அறுவை சிகிச்சை செய்யும் இடத்தில் கொடுக்கப்படும்.

நன்மைகள்

அறுவை சிகிச்சையின்போது ஏற்படும் நாடித்துடிப்பு மற்றும் இரத்த அழுத்த மாற்றங்கள் குறைக்கப்படுகின்றன.

இதர வலி நிராவண மருந்துகளின் தேவைகள் வெகுவாக குறைக்கப்படுகின்றன.

அறுவை சிகிச்சைக்குப்பின்னர் வலி நிவாரணத்தின் தன்மை நீட்டிக்கப்படுகிறது.

பக்கவிளைவுகள்

ஊசி போடும்போது அசௌகரியம் ஏற்படலாம். மரத்துப்போகும் ஊசியின் மூலம் இது தவிர்க்கப்படும்.

அறுவை சிகிச்சையின்போது ஏற்படும் நாடித்துடிப்பு மற்றும் இரத்த அழுத்த மாற்றங்கள் குறைக்கப்படுகின்றன.

இதர வலி நிராவண மருந்துகளின் தேவைகள் வெகுவாக குறைக்கப்படுகின்றன.

பக்கவிளைவுகள்

ஊசி போடும்போது அசௌகரியம் ஏற்படலாம். மரத்துப்போகும் ஊசியின் மூலம் இது தவிர்க்கப்படும்.

குறைந்த இரத்த அழுத்தம், குறைந்த நாடித்துடிப்பு ஏற்படலாம். அதற்கு மாற்று மருந்துகள் உடனடியாக கொடுக்கப்படும்.

இந்த முறையான ஆய்வு ஏற்கனவே பல இடங்களில் நடத்தப்பட்டுள்ளது. மேலும் இதன் பாதுகாப்பு உறுதிசெய்யப்பட்டுள்ளது. நீங்கள் இந்த ஆய்வில் பங்குகொள்ள விரும்பவில்லை என்றால் எப்போதும் உபயோகிக்கப்படும் மருந்தே கொடுக்கப்படும். உங்கள் பாதுகாப்பே எங்களின் முக்கிய நோக்கம்.

இந்த ஆய்வு சம்பந்தமான எல்லா புள்ளி விவரங்கள் மற்றும் நோயாளிகளின் விவரங்கள் ரகசியமாக வைக்கப்படும். இந்த ஆய்வு சம்பந்தப்பட்ட எல்லா பரிசோதனைகள், மருந்துகள் மற்றும் மருத்துவ சேவைகள் அனைத்தும் நோயாளிகளுக்கு இலவசமாக வழங்கப்படும்.

ஆய்வாளரின் பெயர்

பங்குபெறுபவரின் பெயர்

ஆய்வாளரின் கையொப்பம்

பங்குபெறுபவரின் கையொப்பம்

ஆராய்ச்சி ஒப்புதல் படிவம்

ஆராய்ச்சியின் தலைப்பு

மண்டை ஓடு பிளவு அறுவை சிகிச்சையின்போது .25% புபிவெகையின் மருந்துக் கலவையை உச்சிவட்டக் குடுமித் தோல் நரம்புகளுக்கு இடையே செலுத்துவது மற்றும் 0.25% புபிவெகையின் மற்றும் 1:4,00,000 அட்ரினலின் கலவையை அறுவை சிகிச்சை செய்யும் இடத்தில் நேரடியாக செலுத்துவதால் ஏற்படும் வலி நிவாரணத்தையும் ஒப்பிடும்

ஆய்வு

ஆய்வு நிலையம் : மயக்கவியல் துறை, சென்னை மருத்துவக் கல்லூரி
சென்னை - 3.

பங்கு பெறுவரின் பெயர் :

பங்குபெறுபவரின் எண் :

பங்குபெறுபவர் இதனை (✓) குறிக்கவும்

மேலே குறிப்பிட்டுள்ள மருத்துவ ஆய்வின் விவரங்கள் எனக்கு விளக்கப்பட்டது. என்னுடைய சந்தேகங்களை கேட்கவும், அதற்கான தகுந்த விளக்கங்களை பெறவும் வாய்ப்பளிக்கப்பட்டது.

☐

நான் இவ்வாய்வில் தன்னிச்சையாகதான் பங்கேற்கிறேன். எந்த காரணத்தினாலோ எந்த கட்டத்திலும் எந்த சட்ட சிக்கலுக்கும் உட்படாமல் நான் இவ்வாய்வில் இருந்து விலகி கொள்ளலாம் என்றும் அறிந்து கொண்டேன்.

☐

இந்த ஆய்வு சம்பந்தமாகவோ, இதை சார்ந்த மேலும் ஆய்வு மேற்கொள்ளும் போதும் இந்த ஆய்வில் பங்குபெறும் மருத்துவர் என்னுடைய மருத்துவ அறிக்கைகளை பார்ப்பதற்கு என் அனுமதி தேவையில்லை என அறிந்து கொள்கிறேன். நான் ஆய்வில் இருந்து விலகிக் கொண்டாலும் இது பொருந்தும் என அறிகிறேன்.

☐

இந்த ஆய்வின் மூலம் கிடைக்கும் தகவல்களையும், பரிசோதனை முடிவுகளையும் மற்றும் சிகிச்சை தொடர்பான தகவல்களையும் மருத்துவர் மேற்கொள்ளும் ஆய்வில் பயன்படுத்திக்கொள்ளவும் அதை பிரசுரிக்கவும் என் முழு மனதுடன் சம்மதிக்கின்றேன்.

☐

இந்த ஆய்வில் பங்கு கொள்ள ஒப்புக்கொள்கிறேன். எனக்கு கொடுக்கப்பட்ட அறிவுரைகளின்படி நடந்து கொள்வதுடன் 'இந்த ஆய்வை மேற்கொள்ளும் மருத்துவ அணிக்கு உண்மையுடன் இருப்பேன் என்று உறுதியளிகிறேன்.

☐

அறுவை சிகிச்சையின்போது உச்சிவட்ட குடுமித்தோல் நரம்புகளுக்கு இடையே 0.25% புபிவெகையின் கலவை அல்லது அறுவை சிகிச்சை செய்யுமிடத்தில் 0.25% புபிவெகையின் மற்றும் 1:4,00,000 அட்ரினலின் கொடுக்கப்படும் என்பதை அறிந்துகொண்டேன். இதனால் உடலுக்கு எந்தவிதமான உபாதைகளும் இருக்காது என்பதை அறிந்துகொண்டு இந்த ஆய்வில் பங்குபெற முழு மனதுடன் சம்மதிக்கிறேன்.

☐

பங்கேற்பவரின் கையொப்பம் இடம்..... தேதி.....
கட்டைவிரல் ரேகை

பங்கேற்பவரின் பெயர் மற்றும் விலாசம்

ஆய்வாளரின் கையொப்பம் இடம்..... தேதி.....
ஆய்வாளரின் பெயர்

PATIENT CONSENT FORM

Study title : “A Prospective, randomized study comparing the analgesic efficacy of Scalp block with 0.25% Bupivacaine vs Pre Incisional infiltration with 0.25% Bupivacaine with Adrenaline(1:400,000) in patients undergoing Elective Craniotomies”

Study center: Institute of Anaesthesiology & Critical care,
Rajiv Gandhi Government General Hospital,
Madras Medical College,
Chennai.

Participant name :

Age:

Sex:

I.P.No:

I confirm that I have understood the purpose of procedure for the above study .
I have the opportunity to ask the question and all my questions and doubts have been answered to my satisfaction.

I have been explained about the pitfall in the procedure. I have been explained about the safety, advantage and disadvantage of the technique.

I understand that my participation in the study is voluntary and that I am free to withdraw at anytime without giving any reason.

I understand that investigator , regulatory authorities and the ethical committee will not need my permission to look at my health records both in respect to current study and any further research that may be conducted in relation to it, even if I withdraw from the study . I understand that my identity will not be revealed in any information released to third parties or published , unless as required under the law . I agree not to restrict the use of any data or results that arise from the study .

Time:

Date:

Signature / thumb impression of patient

Place:

Patient name:

Signature of the investigator:

Name of the investigator:

PROFORMA

NAME:

DATE:

IP NO:

DIAGNOSIS:

SURGICAL PROCEDURE DONE:

Rs:

g%

Platelets:

PRE OP ASSESSMENT:

HISTORY: Any Co-morbid illness

H/O bleeding diathesis

H/o allergy to local anaesthetics

H/O previous surgeries

MEASURES OF STUDY OUTCOME:

mmHg

sPo2- %

8Hr-

[illegible]

GROUP A	NAME	AGE	SEX	IP NUMBER	WEIGHT	HEIGHT	BMI	ASA	DIAGNOSIS	PROCEDURE	BASLINE	Induction	Block LA	3 AB	3 pin	Incision	Flap Rise	FR 2
1	RAJAKUMARAN	20	M	11203	53	152	22.93975069	I	CSF RHINORRHEA	ANTERIOR CRANIAL FOSSA REPAIR	92	97	103	95	93	90	87	85
2	SHANTHI	30	F	11219	50	150	22.22222222	I	LEFT FRONTAL SOL	CRANIOTOMY AND EXCISION OF SOL	81	87	95	84	85	78	89	80
3	MUTHUADUGU	40	M	11227	49	154	20.66115702	II	FRONTAL DEPRESSED FRACTURE	CRANIOTOMY AND EXCISION OF DEPRESSED SEGMENT	79	85	92	84	83	84	82	78
4	PARVATHAMMAL	50	F	11356	51	150	22.66666667	II	LEFT TEMPORAL SOL	CRANIOTOMY AND EXCISION OF SOL	91	88	104	90	92	87	85	85
5	NEELAKANDAN	25	M	11270	55	156	22.60026298	I	NEGLECTED CEREBRAL ABCESS	CRANIOTOMY AND GRANULOMA EXCISION	82	89	92	85	84	85	79	83
6	KRITHIKA	22	F	11567	52	154	21.92612582	I	FRONTAL CALAVARIAL DEFECT	CRANIOPLASTY	78	85	90	86	81	80	81	75
7	ABDULLAH	34	M	11678	55	158	22.03172568	I	RIGHT FRONTAL SOL	CRANIOTOMY AND EXCISION OF SOL	104	94	112	96	97	96	89	92
8	GOWTHAM	46	M	11135	45	147	20.82465639	II	LEFT FRONTAL CALAVARIAL DEFECT	CRANIOPLASTY	83	89	93	88	89	85	87	85
9	VASUDEVAN	58	M	11298	54	151	23.68317179	II	RIGHT FRONTAL MENINGIOMA	CRANIOTOMY AND EXCISION	77	82	89	81	81	82	80	81
10	SARANYA	60	F	11300	51	150	22.66666667	II	LEFT TEMPORAL SOL	CRANIOTOMY AND EXCISION OF SOL	95	101	104	99	96	93	87	91
11	KUTTIYAMMAL	21	F	11310	50	148	22.82688093	I	RIGHT FRONTAL CALAVARIAL DEFECT	CRANIOPLASTY	84	93	96	88	87	90	91	87
12	POTHUM PONNU	33	F	11312	52	152	22.50692521	I	RIGHT FRONTAL SOL	CRANIOTOMY AND EXCISION OF SOL	76	81	87	83	81	80	82	78
13	KALANITHY	45	M	11324	50	155	20.81165453	II	RIGHT PARIETAL SOL	CRANIOTOMY AND EXCISION OF SOL	93	99	107	100	95	89	88	87
14	KANNAYA	57	M	11336	51	152	22.07409972	II	RIGHT FRONTAL SOL	CRANIOTOMY AND EXCISION OF SOL	85	92	94	90	88	88	87	86
15	SAKTHI	61	F	11348	54	154	22.76943835	II	LEFT TEMPORAL BONE DEFECT	CRANIOPLASTY	75	83	88	81	82	81	84	79
16	ROOBINI	24	F	11360	51	153	21.78649237	I	FRONTAL BONE DEPRESSED FRACTURE	CRANIOTOMY AND ELEVATION OF FRACTURED SEGMENT	94	100	107	98	96	91	88	86
17	KANNAN	36	M	11372	67	162	25.52964487	I	CSF RHINORRHEA	ANTERIOR CRANIAL FOSSA REPAIR	86	92	99	90	89	87	85	82
18	JENNIFER	48	F	11375	54	155	22.47658689	II	FRONTAL CALAVARIAL DEFECT	CRANIOPLASTY	74	82	89	81	80	77	79	83
19	NETAJI	59	M	11380	53	152	22.93975069	II	FRONTAL BONE DEPRESSED FRACTURE	CRANIOTOMY AND ELEVATION OF DEPRESSED SEGMENT	102	92	100	93	90	88	86	87
20	VENKAT	61	M	11385	65	163	24.4646016	II	LEFT TEMPORAL SOL	CRANIOTOMY AND EXCISION OF SOL	87	80	94	82	91	85	87	86
21	CHANDRA	27	F	11390	52	153	22.2136785	I	SELLAR TUMOUR	ANTERIOR CRANIOTOMY AND EXCISION OF SOL	73	77	86	80	81	76	80	79
22	SUGUNA	39	F	11395	57	156	23.42209073	I	RIGHT OCCIPITAL SOL	CRANIOTOMY AND EXCISION OF SOL	97	86	103	88	90	94	90	92
23	RAJASEKAR	41	M	11400	68	164	25.2825699	II	LEFT FRONTAL MENINGIOMA	CRANIOTOMY AND EXCISION	88	93	97	92	89	86	84	86
24	SATHYA	53	F	11404	59	150	26.22222222	II	RIGHT FRONTAL CALAVARIAL DEFECT	CRANIOPLASTY	72	80	85	81	80	77	75	70
25	JANANATHAN	63	M	11408	62	158	24.8357635	II	RIGHT TEMPORO PARIETAL SOL	CRANIOTOMY AND EXCISION OF SOL	96	90	104	91	93	89	83	86
26	AKILANDESWARI	29	F	11412	54	150	24	I	LEFT TEMPORAL SOL	CRANIOTOMY AND EXCISION OF SOL	89	94	101	96	92	85	84	85
27	JEYACHANDRAN	25	M	11416	62	162	23.62444749	I	TEMPORAL BONE DEPRESSED FRACTURE	CRANIOTOMY AND ELEVATION OF DEPRESSED SEGMENT	71	78	85	77	78	76	77	75
28	ANDERSON	33	M	11420	70	168	24.8015873	I	LEFT OCCIPITAL SOL	CRANIOTOMY AND EXCISION OF SOL	98	91	104	90	91	89	87	90
29	PRIYADARSHINI	46	F	11424	59	157	23.93606231	II	LEFT TEMPORAL DEFECT	CRANIOPLASTY	90	95	97	93	89	92	90	87
30	MUNEESSWARAN	50	M	11428	62	165	22.77318641	II	CSF RHINORRHEA	ANTERIOR CRANIAL FOSSA REPAIR	80	87	92	86	82	82	80	78

[illegible]

FR 3	BONE	Dura open	BW 1	BW2	D C	B C	S C	SKINCLO	END	BASELINE SBP	Induction	Block/LA	3 AB	3 pin	Incision	Flap Rise	FR 2	FR 3	BONE	Dura open	BW 1	BW2	D C	B C	S C	SKINCLO	END	BASELINE DBP	Induction
86	90	95	90	89	85	79	80	81	82	120	126	130	118	124	123	120	116	115	121	130	118	116	114	117	122	120	118	85	88
78	77	92	87	85	79	75	74	73	72	118	125	132	117	118	115	122	118	116	114	134	118	115	110	112	116	118	114	76	80
75	76	87	80	81	75	72	71	76	74	135	130	144	132	128	131	126	132	135	132	144	130	126	128	131	134	132	125	80	76
83	88	96	90	88	85	88	86	84	82	142	135	140	154	138	136	140	136	135	138	152	134	132	130	128	131	134	130	78	83
87	86	93	89	87	84	87	83	80	78	115	122	130	114	115	118	116	112	110	111	128	110	108	112	111	114	115	110	60	65
77	80	89	86	85	78	81	82	83	81	124	130	135	123	122	120	118	115	118	117	132	116	114	112	115	118	110	114	81	85
89	91	97	89	90	88	86	87	85	80	126	132	138	125	128	122	124	120	118	121	134	122	118	116	120	117	123	118	77	82
79	82	89	80	85	84	83	79	81	77	138	130	147	132	134	130	132	134	128	126	144	130	128	125	123	127	130	126	74	80
76	79	86	80	82	77	78	74	76	74	144	132	156	140	138	135	143	142	138	136	150	138	135	133	130	128	131	134	90	85
88	92	100	91	92	88	85	86	84	81	134	142	145	128	130	129	132	134	135	128	140	125	126	122	118	121	116	120	82	85
85	82	89	84	80	81	82	79	80	78	124	135	140	126	122	120	118	115	116	118	132	120	119	116	112	114	115	111	65	70
75	72	82	74	73	71	75	70	72	71	130	136	142	134	130	128	126	120	122	124	138	125	123	128	125	119	121	122	79	84
90	88	95	89	87	85	88	84	80	81	121	127	134	125	122	120	118	117	115	116	128	118	115	114	110	112	118	115	68	74
83	84	90	85	87	85	84	83	82	83	136	142	148	140	135	138	132	134	130	131	140	129	132	128	125	126	124	121	84	80
81	83	90	80	82	80	81	78	76	77	142	130	148	132	134	128	126	125	129	130	142	128	132	126	125	120	122	124	81	86
87	85	93	86	87	82	80	79	83	84	150	138	158	140	138	136	142	144	140	143	154	140	138	135	130	136	138	140	88	82
83	85	92	84	82	88	82	81	79	80	146	135	152	144	140	141	138	136	134	138	150	135	128	132	134	131	129	135	83	88
85	84	90	79	82	80	78	77	75	76	131	140	146	134	132	128	126	125	128	126	138	125	128	122	124	126	120	122	75	80
85	86	91	83	85	79	83	85	87	85	128	136	144	135	130	126	125	128	130	126	138	125	122	119	121	118	114	116	77	80
84	85	94	86	85	82	79	77	78	76	125	132	138	128	120	122	118	121	117	123	135	126	124	120	118	115	114	110	72	76
75	78	84	75	77	73	72	71	77	74	108	115	120	112	114	110	111	106	105	106	114	108	105	100	102	104	106	104	66	72
85	90	96	89	90	89	85	87	82	80	110	120	124	116	115	112	110	107	104	108	115	106	102	104	100	105	110	105	73	77
88	84	90	82	79	82	78	81	80	77	129	120	138	122	124	120	125	121	123	126	134	128	124	120	121	118	116	120	81	85
72	71	79	72	74	75	71	69	70	71	135	142	148	128	130	132	127	125	130	132	140	130	128	126	125	128	131	127	84	90
88	85	92	83	81	79	80	82	81	83	122	130	136	128	124	121	120	124	126	125	136	128	124	121	122	118	116	121	70	76
80	81	87	80	79	82	80	78	75	77	128	135	140	122	121	120	118	116	112	119	130	115	116	117	112	114	120	116	91	94
77	72	81	70	72	73	74	69	68	70	148	140	152	142	138	136	135	141	137	134	146	135	130	132	128	126	125	130	85	80
88	85	92	83	85	82	81	83	84	81	125	134	136	130	124	126	122	128	125	121	130	120	116	117	114	118	115	117	62	66
81	84	90	80	82	83	80	79	82	78	116	124	130	118	116	110	112	115	114	118	126	116	114	110	112	111	114	113	73	78
75	76	82	75	76	74	75	73	71	70	124	130	138	116	118	120	121	124	122	115	127	116	120	118	115	114	111	118	75	80

FR 3	BONE	Dura open	BW 1	BW2	D.C	B.C	9.C	SKINCLO	END	BASELINE	Induction	Block/LA	3 AB	3 pin	Incision	Flap Rise	FR 2	FR 3	BONE	Dura open	BW 1	BW2	D.C	B.C	S.C	SKINCLO	END	BASELINE	Induction
84	85	91	83	84	90	92	91	93	95	120	112	130	115	121	118	126	124	120	118	128	121	124	126	123	127	125	130	85	80
88	89	94	88	86	92	89	90	91	92	118	125	132	120	126	120	128	130	126	125	133	122	124	128	130	132	135	134	76	80
87	88	95	86	87	93	92	96	94	95	135	130	140	134	142	136	144	140	142	138	146	135	133	138	142	145	148	146	80	76
96	94	102	90	92	93	95	97	99	102	142	135	144	140	144	136	145	141	140	142	150	140	138	141	144	146	145	144	78	75
88	86	94	85	87	92	91	93	94	92	115	123	128	118	130	124	132	125	122	126	138	125	123	126	128	134	136	135	60	64
85	84	92	85	87	90	89	92	94	91	124	130	136	126	134	130	138	130	126	128	140	125	128	130	133	135	132	136	81	85
95	94	105	93	90	98	100	99	102	101	126	130	135	130	136	135	140	128	124	130	142	126	131	133	134	136	135	137	77	80
86	90	94	86	88	93	90	89	92	91	138	130	144	135	140	137	145	138	136	135	148	136	140	142	145	144	146	143	74	70
94	89	96	88	90	89	91	93	90	91	144	135	150	138	147	140	148	143	139	136	150	140	142	145	148	152	150	151	90	84
95	98	105	96	98	100	102	101	103	99	134	138	144	132	145	139	142	140	136	144	150	140	143	146	148	153	151	150	82	86
88	89	96	87	89	92	94	95	96	93	124	130	134	126	136	132	135	130	128	126	140	128	130	134	136	135	138	140	65	70
92	91	102	90	88	93	94	96	92	93	130	136	140	132	142	131	138	132	134	131	142	128	130	135	132	138	140	141	79	84
99	100	107	98	95	96	94	98	99	102	121	128	130	122	132	128	134	130	127	124	135	122	126	128	132	133	136	135	68	73
87	89	97	88	89	92	91	93	90	94	136	130	142	134	141	136	142	138	135	133	144	132	136	138	142	140	145	143	84	80
89	87	94	86	85	89	88	90	87	89	142	135	146	140	144	135	143	136	138	140	146	138	135	141	144	146	147	145	81	77
98	96	102	95	93	96	97	95	92	96	150	140	152	138	146	136	145	140	142	139	148	140	141	142	136	135	132	134	88	82
84	86	90	85	87	88	91	89	90	92	146	138	150	142	148	143	149	139	135	138	150	136	132	135	140	142	144	143	83	80
93	92	97	90	89	91	93	92	90	94	131	138	144	132	142	134	140	132	135	136	141	132	135	138	136	140	142	144	75	80
96	94	103	92	90	94	95	97	98	96	128	135	140	130	138	132	137	133	130	128	138	135	130	126	125	128	134	138	77	82
88	85	92	86	84	90	88	86	89	92	125	131	136	126	138	133	135	130	126	124	131	122	125	128	132	131	135	137	72	77
92	93	100	94	95	93	96	94	97	98	108	115	118	110	116	110	121	114	112	115	122	114	116	120	121	124	122	125	66	70
88	90	98	91	94	93	97	96	94	95	110	114	120	112	118	114	122	115	116	110	123	111	117	112	114	115	122	124	73	76
84	87	91	85	87	88	90	89	91	93	129	135	142	130	136	128	134	131	135	132	140	134	135	138	130	136	138	137	81	85
96	93	101	92	95	94	92	96	97	95	135	140	143	132	138	128	136	131	137	140	147	142	144	140	146	148	145	146	84	88
95	99	107	98	95	96	99	101	104	103	122	130	134	128	142	135	140	132	130	134	141	136	135	132	138	140	144	145	70	76
80	79	90	82	85	87	90	89	91	92	128	132	140	136	145	138	144	140	137	141	148	140	144	145	148	146	143	148	91	94
84	87	91	85	87	88	90	89	91	93	148	140	155	152	160	144	156	150	152	151	161	150	147	155	158	160	157	156	85	81
96	93	101	92	95	94	92	96	97	95	125	130	134	132	142	128	140	132	130	127	144	136	138	144	141	145	148	146	62	68
95	99	107	98	95	96	99	101	104	103	116	122	125	120	128	123	130	120	122	125	131	124	127	132	130	128	126	132	73	77
80	79	90	82	85	87	90	89	91	92	124	130	134	126	140	128	137	130	132	134	141	135	136	140	138	132	134	137	75	80

Block/LA	3 AB	3 pin	Incision	Flap Rise	FR 2	FR 3	BONE	Dura open	BW 1	BW2	D C	B.C	S C	SKINCLO	END	Baseline MAP	Induction	Block/LA	3 AB	3 pin	Incision	Flap Rise	FR 2	FR 3	BONE	Dura open	BW 1	BW2	D C
90	84	86	83	82	80	81	80	90	87	85	84	86	82	83	83	83	100.54	103.2	95.22	98.54	96.2	94.54	91.88	92.22	93.53	103.2	97.23	95.23	93.9
84	75	76	77	74	76	73	72	76	74	76	75	70	71	73	72	72.33	94.85	99.84	88.86	89.86	89.54	89.84	89.86	87.19	85.86	95.14	88.52	88.87	86.55
85	78	77	79	78	77	76	77	82	78	75	76	78	80	74	75	74.67	93.82	104.47	95.82	93.83	96.16	93.84	95.15	95.47	95.15	102.46	95.16	91.83	93.16
86	80	76	75	77	78	79	80	88	82	81	77	75	76	73	74	73.67	100.16	103.82	104.42	96.46	95.13	97.79	97.14	97.48	99.14	109.12	99.16	97.83	94.49
68	62	61	60	63	65	66	61	70	62	64	60	58	56	59	62	61.01	83.81	88.46	79.16	78.82	79.14	80.49	80.51	80.52	77.5	89.14	77.84	78.52	77.16
88	82	84	83	85	86	83	80	78	79	76	77	74	75	78	76	76.66	99.85	103.51	95.53	96.54	95.21	95.89	95.57	94.55	92.21	95.82	91.21	88.54	88.55
85	80	78	75	76	74	77	76	86	75	74	76	72	73	70	72	71.34	98.5	102.49	94.85	94.5	90.51	91.84	89.18	90.53	90.85	101.84	90.51	88.52	89.2
83	75	76	74	77	72	73	71	80	72	70	68	70	69	71	70	70.33	96.5	104.12	93.81	95.14	92.48	95.15	92.46	91.15	89.15	101.12	91.14	89.14	86.81
92	84	82	80	81	83	82	80	88	81	82	79	83	84	80	82	81.34	100.51	113.12	102.48	100.48	98.15	101.46	102.47	100.48	98.48	108.46	99.81	99.49	96.82
92	83	80	81	82	78	77	79	87	80	76	78	77	79	76	78	77.34	103.81	109.49	97.85	96.5	96.84	98.5	96.48	96.14	95.17	104.49	94.85	92.5	92.52
76	66	65	67	68	66	64	65	74	67	65	68	66	64	60	62	61.34	91.45	97.12	85.8	83.81	84.49	84.5	82.17	81.16	82.49	93.14	84.49	82.82	83.84
90	80	82	81	79	77	78	80	92	81	78	76	77	79	75	74	74.33	101.16	107.16	97.82	97.84	96.51	94.51	91.19	92.52	94.52	107.18	95.52	92.85	93.16
80	70	68	69	66	64	65	62	75	64	65	63	60	61	64	63	63.33	91.49	97.82	88.15	85.82	85.83	83.16	81.49	81.5	79.82	92.49	81.82	81.5	79.83
91	85	83	84	80	82	81	83	94	85	83	82	80	81	79	78	78.33	100.46	109.81	103.15	100.16	101.82	97.16	99.16	97.17	98.84	109.18	99.52	99.17	97.18
90	82	80	76	79	78	77	75	88	78	75	76	77	74	72	73	72.67	100.52	109.14	98.5	97.82	93.16	94.51	93.51	94.16	93.15	105.82	94.5	93.81	92.5
95	84	80	82	83	81	79	78	90	80	82	79	77	78	76	77	76.67	100.48	115.79	102.48	99.14	99.82	102.47	101.79	99.13	99.45	111.12	99.8	100.48	97.48
94	82	80	81	83	79	78	77	91	80	82	79	77	78	75	76	75.67	103.51	113.14	102.46	99.8	100.8	101.15	97.81	96.48	97.13	110.47	98.15	97.18	96.49
85	76	78	74	77	79	75	72	84	74	70	71	73	70	69	68	68.33	99.8	105.13	95.14	95.82	91.82	93.17	94.18	92.49	89.82	101.82	90.83	89.14	87.83
88	78	85	76	84	80	77	78	90	80	81	83	82	85	84	86	85.34	98.48	106.48	96.81	99.85	92.5	97.53	95.84	94.49	93.84	105.84	94.85	94.53	94.88
80	70	71	72	69	68	65	66	80	68	65	67	66	64	67	66	66.33	94.48	99.14	89.14	87.17	88.5	85.17	85.49	82.16	84.81	98.15	87.14	84.47	84.49
77	65	68	66	64	67	65	63	75	64	62	60	61	63	62	60	60.66	86.19	91.19	80.51	83.18	80.52	79.51	79.87	78.2	77.19	87.87	78.52	76.19	73.2
85	72	74	70	72	71	73	69	80	70	72	71	68	65	67	66	66.33	91.19	97.87	86.52	87.53	83.86	84.54	82.88	83.23	81.87	91.55	81.88	81.9	81.89
92	80	78	77	79	80	76	75	86	74	73	70	72	71	73	74	73.67	96.55	107.18	93.86	93.18	91.19	94.18	93.53	91.51	91.83	101.84	91.82	89.83	86.5
95	85	83	84	80	82	81	83	92	80	78	81	79	82	80	79	79.33	107.16	112.49	99.19	98.51	99.84	95.51	96.19	97.17	99.17	107.84	96.5	94.5	95.65
82	72	70	68	67	69	71	68	81	70	66	68	67	65	63	64	63.67	93.82	99.82	90.48	87.82	85.49	84.49	87.15	89.15	86.81	99.15	89.14	85.14	85.49
98	90	88	87	89	86	85	88	92	86	84	85	82	80	81	79	79.66	107.53	111.86	100.56	98.89	97.89	98.57	95.9	93.91	98.23	104.54	95.57	94.56	95.56
91	84	86	85	83	82	80	81	94	82	80	78	79	77	75	76	75.67	99.8	111.13	103.14	103.16	101.83	100.16	101.47	98.81	98.49	111.16	99.49	96.5	95.82
73	64	62	61	63	60	62	59	70	61	58	60	56	58	57	55	55.66	88.44	93.79	85.78	82.46	82.45	82.47	82.44	82.79	79.46	89.8	80.47	77.14	78.81
82	75	74	71	70	72	69	68	80	69	67	68	65	64	66	67	66.67	93.18	97.84	89.19	87.86	83.87	83.86	86.19	83.85	84.5	95.18	84.51	82.51	81.86
86	76	74	75	73	71	72	70	82	72	70	68	69	67	65	66	65.67	96.5	103.16	89.2	88.52	89.85	88.84	88.49	88.5	84.85	96.85	86.52	86.5	84.5

Block/LA	3 AB	3 pin	Incision	Flap Rise	FR 2	FR 3	BONE	Dura open	BW 1	BW2	D.C	B.C	S.C	SKINCLO	END	BASELINE	Induction	Block/LA	3 AB	3 pin	Incision	Flap Rise	FR 2	FR 3	BONE	Dura open	BW 1	BW2	D.C
92	84	90	83	91	85	82	84	94	83	86	88	87	90	92	93	92.67	90.56	104.54	94.23	100.23	94.55	102.55	97.87	94.54	95.22	105.22	95.54	98.54	100.54
88	78	85	80	86	79	81	83	89	82	85	84	86	88	87	85	85.66	94.85	102.52	91.86	98.53	93.2	99.86	95.83	95.85	96.86	103.52	95.2	97.87	98.52
88	82	90	81	87	80	83	82	91	83	81	84	87	86	85	90	88.35	93.82	105.16	99.16	107.16	99.15	105.81	99.8	102.47	100.48	109.15	100.16	98.16	101.82
83	80	86	79	88	81	79	83	92	84	86	86	88	87	90	92	91.34	94.8	103.13	99.8	105.14	97.81	106.81	100.8	99.13	102.47	111.14	102.48	103.16	104.15
70	62	69	61	72	63	65	64	75	63	66	68	72	69	71	69	69.66	83.47	89.14	80.48	89.13	81.79	91.8	83.46	83.81	84.46	95.79	83.46	84.81	87.14
90	82	89	80	92	85	83	84	93	85	87	86	88	90	93	90	90.99	99.85	105.18	96.52	103.85	96.5	107.18	99.85	97.19	98.52	108.51	98.2	100.53	100.52
85	78	86	79	87	80	83	81	92	82	84	86	85	88	86	87	86.67	96.5	101.5	95.16	102.5	97.48	104.49	95.84	96.53	97.17	108.5	96.52	99.51	101.51
65	76	87	75	90	78	81	80	91	82	84	87	85	88	90	91	90.67	89.8	104.47	95.47	104.49	95.46	108.15	97.8	99.15	98.15	109.81	99.82	102.48	105.15
93	88	95	87	94	86	89	91	98	90	94	93	95	92	96	92	93.32	100.83	111.81	104.5	112.16	104.49	111.82	104.81	105.5	105.85	115.16	106.5	109.84	110.16
91	83	90	81	93	83	85	84	96	88	87	90	93	92	91	95	93.68	103.16	108.49	99.17	108.15	100.14	109.17	101.81	101.83	103.8	113.82	105.16	105.48	108.48
73	66	75	68	77	67	70	72	80	71	73	75	74	76	78	77	77.33	89.8	93.13	85.8	95.13	89.12	96.14	87.79	89.14	89.82	99.8	89.81	91.81	94.47
88	80	90	82	92	78	81	83	94	85	84	86	88	87	89	91	90.34	101.16	105.16	97.16	107.16	98.17	107.18	95.82	98.49	98.64	109.84	99.19	99.18	102.17
79	70	81	72	84	69	71	72	85	73	75	74	78	76	80	82	81.34	91.15	95.83	87.16	97.83	90.48	100.5	89.13	89.48	89.16	101.5	89.17	91.83	91.82
92	82	90	81	93	83	85	84	95	86	89	87	88	91	90	92	91.34	96.5	108.5	99.16	106.83	99.15	109.17	101.15	101.5	100.17	111.17	101.18	104.51	103.83
89	80	90	82	92	85	83	84	94	85	87	86	90	89	88	91	90.01	96.14	107.81	99.8	107.82	99.49	108.83	101.83	101.15	102.48	111.16	102.49	102.84	104.15
94	86	85	87	84	80	82	83	92	84	82	79	80	81	83	82	82.33	101.14	113.14	103.16	105.13	103.17	104.13	99.8	101.8	101.48	110.48	102.48	101.47	99.79
91	82	94	81	92	84	81	83	95	85	87	86	88	90	89	87	87.66	99.14	110.47	101.8	111.82	101.46	110.81	102.15	98.82	101.15	113.15	101.83	101.85	102.17
84	76	85	74	83	77	79	80	91	82	85	83	84	86	85	87	86.34	99.14	103.8	94.48	103.81	93.8	101.81	95.15	97.48	98.48	107.5	98.5	101.5	101.15
87	80	90	79	89	78	80	82	95	81	84	82	86	85	88	90	89.34	99.49	104.49	96.5	105.84	96.49	104.84	96.15	96.5	97.18	109.19	98.82	99.18	96.52
81	74	85	73	86	75	77	76	88	74	77	80	79	82	81	83	82.34	94.82	99.15	91.16	102.49	92.8	102.17	93.15	93.17	91.84	102.19	89.84	92.84	95.84
73	65	76	67	78	70	73	72	83	74	76	75	79	78	80	82	81.34	84.85	87.85	79.85	89.2	81.19	92.19	84.52	85.87	86.19	95.87	87.2	89.2	89.85
82	74	85	75	88	76	78	77	90	76	80	79	77	81	83	82	82.33	88.54	94.54	86.54	95.89	87.87	99.22	88.87	90.54	87.89	100.89	87.55	92.21	89.89
92	80	88	78	91	79	82	84	95	81	85	87	86	88	90	89	89.33	101.5	108.5	96.5	103.84	94.5	105.19	96.16	99.49	99.84	109.85	98.49	101.5	103.83
93	85	92	83	95	86	88	87	96	86	88	87	89	91	90	92	91.34	105.16	109.5	100.51	107.18	97.85	108.53	100.85	104.17	104.49	112.83	104.48	106.48	104.49
82	72	80	71	83	73	75	74	85	76	79	78	80	82	81	83	82.34	93.82	99.16	90.48	100.46	92.12	101.81	92.47	93.15	93.8	103.48	95.8	97.48	95.82
98	90	97	88	99	91	89	92	100	90	93	91	92	95	94	93	93.33	106.54	111.86	105.18	112.84	104.5	113.85	107.17	104.84	108.17	115.84	106.5	109.83	108.82
94	86	95	87	97	88	90	89	98	88	87	90	89	92	91	94	93.01	100.47	114.13	107.78	116.45	105.81	116.47	108.46	110.46	109.46	118.79	108.46	106.8	111.45
75	64	74	66	76	67	69	68	80	71	70	73	72	74	75	76	75.67	88.46	94.47	86.44	96.44	86.46	97.12	88.45	89.13	87.47	101.12	92.45	92.44	96.43
80	72	83	74	85	73	76	74	88	75	78	77	76	80	81	79	79.66	91.85	94.85	87.84	97.85	90.17	99.85	88.51	91.18	90.83	102.19	91.17	94.17	95.15
87	77	88	76	89	78	80	84	90	85	83	86	84	82	87	85	85.66	96.5	102.51	93.17	105.16	93.16	104.84	95.16	97.16	100.5	106.83	101.5	100.49	103.82

B.C	S.C	SKINCLO	END	FENT	0 MINS	0.5 HOUR	1 HOUR	1.5 HOUR	2 HOUR	2.5 HOUR	3 HOUR	3.5 HOUR	4 HOUR	4.5 HOUR	5 HOUR	5.5 HOUR	6 HOUR	8 HOUR	10 HOUR	14 HOUR	18 HOUR	22 HOUR	DURATION OF ANALGESIA	IFR	SR
96.23	95.2	95.21	94.55	150	2	2	2	2	2	2	2	2	2	3	3	3	3	4	5	3	3	3	600	600	NIL
83.86	85.85	87.85	85.86	150	1	1	1	1	1	2	2	2	2	3	3	3	4	5	3	3	3	3	480	480	NIL
95.49	97.82	93.14	91.5	140	2	2	2	2	2	2	2	3	3	3	3	3	3	4	5	3	3	3	600	600	NIL
92.49	94.15	93.13	92.48	150	1	1	1	1	2	2	2	2	3	3	3	3	4	5	3	3	3	4	480	480	NIL
75.49	75.14	77.48	77.84	140	1	1	1	1	1	2	2	2	2	2	3	3	3	4	5	2	3	3	600	600	NIL
87.53	89.19	88.56	88.54	120	1	1	1	1	1	2	2	2	2	3	3	3	4	5	3	3	3	3	480	480	NIL
87.84	87.52	87.49	87.18	140	1	1	1	1	2	2	2	2	2	2	3	3	3	4	5	2	2	3	600	600	NIL
87.49	88.14	90.47	88.48	120	1	1	2	2	2	2	2	2	2	2	3	3	4	5	3	3	3	4	480	480	NIL
98.51	98.52	96.83	99.16	150	1	1	1	1	1	2	2	2	2	3	3	3	3	4	5	3	3	3	600	600	NIL
90.53	92.86	89.2	91.86	140	1	1	1	1	1	2	2	2	2	3	3	3	3	4	5	3	3	3	600	600	NIL
81.18	80.5	78.15	78.17	140	1	1	1	1	2	2	2	2	2	3	3	3	4	5	3	3	3	4	480	480	NIL
92.84	92.2	90.18	89.84	140	2	2	2	2	2	2	2	2	2	3	3	3	4	5	3	3	3	4	480	480	NIL
76.5	77.83	81.82	80.16	130	1	1	1	1	1	2	2	2	2	2	3	3	3	4	5	3	3	4	600	600	NIL
94.85	95.85	93.85	92.19	140	1	1	1	1	1	2	2	2	2	2	3	3	3	4	5	3	3	4	600	600	NIL
92.84	89.18	88.5	89.83	130	1	1	1	1	2	2	2	2	2	2	2	3	3	4	5	3	3	3	600	600	NIL
94.49	97.14	96.46	97.79	120	1	1	1	1	2	2	2	2	2	2	2	3	3	4	5	3	3	3	600	600	NIL
95.81	95.49	92.82	95.47	150	1	1	1	1	1	2	2	2	2	2	3	3	4	5	3	3	3	4	480	480	NIL
89.83	88.48	85.83	85.82	140	1	1	1	1	1	2	2	2	2	2	3	3	4	5	3	3	3	4	480	480	NIL
94.87	95.69	93.9	95.9	140	2	2	2	2	2	2	2	2	2	3	3	3	4	5	3	3	3	4	480	480	NIL
83.16	80.83	82.51	80.52	160	1	1	1	1	1	2	2	2	2	2	3	3	3	4	5	3	3	4	600	600	NIL
74.53	76.53	76.52	74.52	140	1	1	1	1	1	2	2	2	2	3	3	3	3	4	5	3	3	3	600	600	NIL
78.56	78.2	81.19	78.87	140	2	2	2	2	2	2	2	2	2	3	3	3	3	4	5	3	3	4	600	600	NIL
88.17	86.51	87.19	89.18	150	1	1	1	2	2	2	2	2	2	3	3	3	3	4	5	3	3	3	600	600	NIL
94.18	97.18	96.83	94.84	150	2	2	2	2	2	2	2	2	2	3	3	3	4	5	3	3	3	4	480	480	NIL
85.15	82.49	80.49	82.81	160	1	1	1	1	1	2	2	2	2	2	3	3	3	4	5	3	3	3	600	600	NIL
91.9	91.22	93.87	91.21	140	2	2	2	2	2	2	2	2	2	2	3	3	3	4	5	3	3	3	600	600	NIL
95.17	93.17	91.5	93.82	150	1	1	1	1	1	2	2	2	2	3	3	3	4	5	3	3	3	4	480	480	NIL
75.14	77.8	76.14	75.46	160	2	2	2	2	2	2	2	2	2	2	3	3	3	4	5	3	3	4	600	600	NIL
80.51	79.51	81.84	82.18	150	1	1	1	1	1	2	2	2	2	2	3	3	3	4	5	3	3	3	600	600	NIL
84.18	82.51	80.18	83.16	150	1	1	1	1	1	2	2	2	2	2	2	3	4	5	3	3	3	3	480	480	NIL

B.C	S.C	SKINCLO	END	FENT	0 MINS.	0.5 HOUR	1 HOUR	1.5 HOUR	2 HOUR	2.5 HOUR	3 HOUR	3.5 HOUR	4 HOUR	4.5 HOUR	5 HOUR	5.5 HOUR	6 HOUR	8 HOUR	10 HOUR	14 HOUR	18 HOUR	22 HOUR	DURATION	FR	SR
98.88	102.21	102.89	105.21	200	3	3	3	4	5	3	3	3	3	3	3	4	4	5	3	3	3	3	120	120	480
100.52	102.52	102.84	101.17	210	4	4	5	3	3	3	3	3	3	3	3	4	5	3	3	3	3	4	60	60	360
105.15	105.47	105.79	108.48	210	3	3	3	4	5	3	3	3	3	3	4	4	4	5	3	3	3	4	120	120	480
106.48	106.47	108.15	109.16	210	4	4	5	3	3	3	3	3	3	3	3	4	4	5	3	3	3	4	60	60	480
90.48	90.45	92.45	90.78	220	3	3	3	4	5	3	3	3	3	3	3	3	3	4	5	3	3	4	120	120	600
102.85	104.85	105.87	105.18	180	3	3	3	4	5	3	3	3	3	3	3	3	4	4	5	3	4	4	120	120	600
101.17	103.84	102.17	103.5	200	4	4	5	3	3	3	3	3	3	3	3	4	4	5	3	3	4	4	60	60	480
104.8	106.48	108.48	108.16	210	4	4	5	3	3	3	3	3	3	3	3	4	4	5	3	3	4	4	60	60	480
112.49	111.8	113.82	111.47	190	3	3	3	4	5	3	3	3	3	4	3	3	3	4	5	3	3	4	120	120	600
111.15	112.13	110.8	113.15	180	3	3	3	4	5	3	3	3	3	3	3	3	4	5	3	3	4	4	120	120	480
94.46	95.47	97.8	97.79	190	4	4	5	3	3	3	3	3	3	3	3	4	5	3	3	3	4	4	60	60	360
102.52	103.83	105.83	107.5	180	4	4	5	3	3	3	3	3	3	3	3	4	5	3	3	3	4	4	60	60	360
95.82	94.81	98.48	99.49	200	4	4	5	3	3	3	3	3	3	3	3	4	5	3	3	3	4	4	60	60	360
105.82	107.17	108.15	108.83	200	3	3	3	4	5	3	3	3	3	3	3	3	3	4	5	3	4	4	120	120	600
107.82	107.81	107.47	108.82	170	3	3	3	4	5	3	3	3	3	3	3	3	3	4	5	3	4	4	120	120	360
98.48	98.82	99.17	99.16	170	3	3	3	4	5	3	3	3	3	3	3	4	4	5	3	3	3	4	120	120	480
105.16	107.16	107.15	105.48	180	3	3	3	4	5	3	3	3	3	3	3	4	4	5	3	3	3	4	120	120	480
101.16	103.82	103.81	105.81	170	3	3	3	4	5	3	3	3	3	3	3	4	4	5	3	3	3	4	120	120	480
98.87	99.19	103.18	105.84	180	4	4	5	3	3	3	3	3	3	3	3	4	4	5	3	3	4	4	60	60	480
96.49	98.17	98.82	100.82	190	4	4	5	3	3	3	3	3	3	3	3	4	5	3	3	3	4	4	60	60	360
92.86	93.18	93.86	96.19	170	4	4	5	3	3	3	3	3	3	3	3	4	5	3	3	3	4	4	60	60	360
89.21	92.22	95.87	95.86	180	3	3	3	4	5	3	3	3	3	3	3	4	4	5	3	3	4	4	120	120	480
100.52	103.84	105.84	104.84	200	3	3	3	4	5	3	3	3	3	3	3	3	4	4	5	3	3	4	120	120	600
107.81	109.81	108.15	109.82	160	3	3	3	4	5	3	3	3	3	3	3	4	4	5	3	3	4	4	120	120	480
99.14	101.14	101.79	103.46	200	4	4	5	3	3	3	3	3	3	3	4	4	5	3	3	3	4	4	60	60	360
110.48	111.83	110.17	111.15	180	4	4	5	3	3	3	3	3	3	3	3	4	5	3	3	3	4	4	60	60	360
111.77	114.44	112.78	114.46	170	3	3	3	4	5	3	3	3	3	3	3	4	4	5	3	3	3	4	120	120	480
94.77	97.43	99.09	99.1	190	3	3	3	4	5	3	3	3	3	3	3	4	4	5	3	3	4	4	120	120	480
93.82	95.84	95.85	96.49	180	3	3	3	4	5	3	3	3	3	3	3	3	4	4	5	3	3	3	120	120	600
101.82	98.5	102.51	102.16	190	3	3	3	4	5	3	3	3	3	3	3	4	4	5	3	3	4	4	120	120	480